

Redacted Data Submitted by the Primary Manufacturer and Other Interested Parties for Stelara

Below are redacted versions of the data submitted by the Primary Manufacturer and other interested parties in response to the Negotiation Program information collection request.¹ These redacted data have been redacted consistent with the confidentiality standards described in section 40.2 of the revised guidance and do not contain proprietary information, protected health information (PHI)/personally identifiable information (PII), or other information that is protected from disclosure under applicable law.

Respondents were permitted to include citations and attachments (hereinafter, collectively called “supplemental materials”) within their submissions for certain questions specified in the information collection request; therefore, you may observe that the number and order of any supplemental materials included as part of each response below will vary.

¹ The Negotiation Program information collection request is available on the Office of Management and Budget’s (OMB’s) website at the following link: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202306-0938-013 and described in section 50 of revised guidance.

Section 1194(e)(1) Data Factors
IPAY Year: 2026
Manufacturer: Janssen Biotech Inc.
Drug: Stelara (Ustekinumab)
<p>Background: For the first year of the Medicare Drug Price Negotiation Program (“the Negotiation Program”), CMS selected 10 Part D high expenditure, single source drugs for negotiation. Section 1194(e) of the Act requires Centers for Medicare & Medicaid Services (CMS) to consider two sets of factors as the basis for determining the offer and counteroffer throughout the negotiation process: (1) certain data that must be submitted by the manufacturer of each drug selected for negotiation and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug. After entering into an agreement under the Negotiation Program with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug submitted to CMS the following information with respect to a selected drug: information that CMS required to carry out negotiation, including but not limited to the factors listed in section 1194(e)(1) of the Act. For IPAY 2026, the Primary Manufacturer of each selected drug were tasked to provide the following data factors for each of its selected drug(s), which were specifically:</p> <ul style="list-style-type: none"> C: Research and Development Costs and Recoupment, D: Current Unit Costs of Production and Distribution, E: Prior Federal Financial Support, F: Patents, Exclusivities, and Approvals, and G: Market Data and Revenue and Sales Volume Data. <p>The Primary Manufacturer is responsible for aggregating and reporting all necessary data on its selected drug(s) from other parties, as applicable.</p> <p>Disclaimers: With the exclusion of publicly available data, all manufacturer submitted data is considered proprietary and confidential. The data contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document.</p>

Note: Primary Manufacturers submitted required data in the Health Plan Management System (HPMS). Please note that the format of manufacturer responses is dependent on the data element requested. For example, some requested responses are “yes or no”, while other response options in HPMS provided a drop-down menu. However, some responses could be more complex and subjective, such as dollar

amounts, cost per unit, etc. For many questions, the ICR instructs the manufacturer to include an explanation. In some instances, an explanation is required and in other instances, the ICR directs the user to include an explanation “as necessary.” CMS instructs manufacturers to indicate “n/a” if they choose not to include an explanation in this case.

C. Research and Development Cost							
Description: Section C contains five questions, related to different types of R&D costs incurred by the Primary Manufacturer, including acquisition costs. Each of these questions required the Primary Manufacturer to report, as applicable: (1) dollar amounts for R&D costs, which must be reported in the numerical response field and (2) explanations of how those costs were calculated in the free response field. Section C also contains one question about the Primary Manufacturer’s global and U.S. total lifetime net revenue for the selected drug. This question required the Primary Manufacturer to report, as applicable: (1) the dollar amount for global, total lifetime net revenue, which must be reported in the numerical response field, (2) an explanation of how this amount was calculated in the free response field, (3) the dollar amount for U.S. lifetime net revenue, which must be reported in the numerical response field, and (4) an explanation of how this amount was calculated in the free response field.							
Primary Manufacturer Acquisition Costs of the Selected Drug	Total Acquisition Costs for the Selected Drug	Basic Pre-Clinical Research for All Approved Indications of the Selected Drug	Post-IND Costs for All Approved Indications of the Selected Drug	Costs of Failed or Abandoned Products Related to the Selected Drug	Direct Costs of Other R&D for the Selected Drug Not Accounted for Above	Global Total Lifetime Net Revenue for the Selected Drug	U.S. Total Lifetime Net Revenue for the Selected Drug

Explanations:

Explanation of Allocation of Total Acquisition Costs for the Selected Drug

Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA

Please note that the adjusted data elements as of December 22, 2023 are in response to the email from CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov> with the subject “RE: Janssen Biotech, Inc. section 1194(e)(1) Data Submission Follow-up” received on December 14, 2023 – and includes the requested adjustments to Topic (1) and Topic (2).

The following free text was entered as part of our original HPMS submission for these data elements, and the previously referenced email provides context regarding the requested data element adjustments.

Regarding “Primary Manufacturer Acquisition Costs of the Selected Drug”, the rights to the STELARA BLA were acquired from Centocor, Inc. in 1999.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

It should be noted that responses to Section C do not represent the full cost incurred by Janssen for STELARA. This does not include full investment, and excludes R&D overhead, Cost of Goods sold over the life of the product, as well as ongoing Operating expenses such as Sales & Marketing, as well as Infrastructure Overhead.

[REDACTED]

Explanation of Basic Pre-Clinical Research Costs

Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA

[REDACTED]

Explanation of Post-IND Costs

Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA

Regarding “Post-IND Costs for All Approved Indications of the Selected Drug”, and consistent with ICR guidance, these costs include direct development costs for FDA approved indications of Psoriasis (PsO), Crohn's Disease (CD), Ulcerative Colitis (UC), and Psoriatic Arthritis (PsA). These direct costs include Global Clinical Operations, product development and supply, quantitative sciences, and other direct functional costs. The approved indications did not receive early approvals or receive accelerated approvals. In addition, there are direct costs for Post-Marketing trials of the approved indications in PsO, PsA, UC, and CD, coupled with FDA required direct costs of ongoing pediatric studies primarily in UC, CD and Psoriatic Arthritis (PsA), indications [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Explanation of Costs on Allowable

Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. Regarding “Costs of Failed or Abandoned Products Related to the Selected Drug”, and consistent with ICR guidance, this figure reflects direct costs in failed or abandoned programs for STELARA which includes Billiary Cirrhosis, Multiple Sclerosis, Derm, Type 1 Diabetes, Atopic Dermatitis, Sarcoidosis, COVID-19, Rheumatoid Arthritis, Pediatric SLE, Lupus, and Axial Spondyloarthritis. These programs have the same mechanism of action as the selected drug to target different areas of the body. Moreover, direct costs reported includes failed or abandoned products in the same therapeutic class as the selected drug that did not achieve FDA approval such as PsO Modulator, IL-23 (CD and UC), TYK2 inhibitor (PsO), CSF-1R/FMS inhibitor (CD), P2X7 antagonist (CD), Tesnatilimab (CD & UC), Izencitinib (CD & UC), PD-1 (UC), and TNFA/IL-17 (PsA). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Annual Spend by Year is broken out below in USD inclusive of Cost of Capital adjustments:

[REDACTED]

Annual Spend by Year is broken out below in USD, excluding the Cost of Capital adjustments:

[REDACTED]

[REDACTED]

Explanation of Costs of Other R&D

"Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA

Please note that the adjusted data elements as of December 22, 2023 are in response to the email from CMS IRA Rebate and Negotiation <IRARebateandNegotiation@cms.hhs.gov> with the subject "RE: Janssen Biotech, Inc. section 1194(e)(1) Data Submission Follow-up" received on December 14, 2023 – and includes the requested adjustments to Topic (1) and Topic (2).

The following free text was entered as part of our original HPMS submission for these data elements, and the previously referenced email provides context regarding the requested data element adjustments.

Consistent with ICR guidance, "Direct Costs of Other R&D for the Selected Drug Not Accounted for Above" includes life cycle management studies, feasibility of molecule, improvement of manufacturing process, efficiency, capacity, and yield, shelf life extension, activating additional capacity to meet demand, selection of various resins within the manufacturing process, and Medical Affairs studies in approved indications of PsO, PsA, CD, and UC. [REDACTED]

Annual Spend by Year is broken out below in USD inclusive of Cost of Capital adjustments:

Annual Spend by Year is broken out below in USD, excluding the Cost of Capital adjustments:

Explanation of Global Lifetime Net Revenue

Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA.

These figures conform with GAAP Accounting Standard Certification (ASC) 830 for translating foreign currencies and are consistent with External disclosures.

[REDACTED]

[REDACTED]

[REDACTED]

Explanation of U.S. Lifetime Net Revenue

Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. [REDACTED]

[REDACTED] These figures conform with GAAP Accounting Standard Certification (ASC) 830 for translating foreign currencies and are consistent with External disclosures.

Third Party Royalties deducted from Net Revenue were paid to three licensors as follows. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In the case of all three license agreements the royalties are paid to the licensors [REDACTED]

[REDACTED] Third party royalties are included in the P&L of Janssen Biotech, Inc. as a part of Cost of Goods Sold (OCNIS - Other Costs Not In Standard). Third Party Royalty figures conform with GAAP Accounting Standard Certification (ASC) 830 for translating foreign currencies and are consistent with External disclosures.

Commercial Milestones are capitalized to the balance sheet and amortized to the P&L (OCNIS) over the life of the patent.

D. Current Unit Costs of Production and Distribution				
Background: Manufacturers were required to report production and distribution unit costs separately for each NDC-11 of the selected drug, including any NDC-11 of the selected drug marketed by a Secondary Manufacturer. A free response field was provided to explain the methodology for calculating the amount reported.				
NDC-11	Average Per Unit Production Cost	Average Per Unit Distribution Costs	Indicate Unit Used	Total Unit Volume
57894-0054-27			ML	
57894-0060-02			ML	
57894-0060-03			ML	
57894-0061-03			ML	
57894-0060-04			ML	
57894-0061-04			ML	
57894-0054-16			ML	
57894-0061-02			ML	

Explanations: Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. Please note that the adjusted data elements as of December 22, 2023 are in response to the email from CMS IRA Rebate and Negotiation <IRAREbateandNegotiation@cms.hhs.gov> with the subject “RE: Janssen Biotech, Inc. section 1194(e)(1) Data Submission Follow-up” received on December 14, 2023 – and includes the requested adjustments to Topic (1) and Topic (2).

The following free text was entered as part of our original HPMS submission for these data elements, and the previously referenced email provides context regarding the requested data element adjustments.

Eight NDC-11s for “STELARA” are included in the “Selected Drug List for Initial Price Applicability Year (IPAY) 2026”. All eight NDC-11s are included in this submission.

Four NDC-11s with total package unit volume “0” were “not marketed, sold, or distributed”. For purposes of instructional compliance, rows were added to – “enter “0” in the total unit volume field and left blank for other calculated fields. These four NDCs are:

Three NDC-11s are sample NDCs under Janssen Biotech, Inc. (“JBI”) labeler 57894: 57894-0060-04, 57894-0061-04, 57894-0054-16; Rows were added to – “enter “0” in the total unit volume field and left blank for other calculated fields.

One NDC-11 (57894-0061-02) under JBI labeler 57894 is an inactive NDC. This NDC had a market end date of September 30, 2009 on the DailyMed website. This NDC-11 did not have sales and is not listed on the FDA website.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

E. Federal Financial Support

Description: This section pertains to all prior federal financial support provided by federal agencies or federally supported grants or contracts that contributed to direct costs for the basic pre-clinical research and clinical trials phase of research and development for FDA-approved indications of the selected drug to the Primary Manufacturer only. It also pertains to prior federal financial support received for indirect costs of developing the selected drug.

Total Federal Financial Support	Federal Financial Support	Type of Agreement	Federal Agency(ies) Participating in Agreement	Nature of Agreement
		Other	Other	

Explanations: Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. "Federal Financial Support" is comprised entirely of IRC 41, credit for increasing research activities for US corporate income tax. The Orphan Drug credit under IRC 45C is not applicable to this analysis because STELARA does not qualify by statute nor has JBI filed to receive orphan drug designation from the FDA for the selected drug.

[REDACTED]

[REDACTED]

Consistent with ICR guidance, no adjustment has been made for federal financial support in questions 2 through 5, as the research tax credit is not specific to the costs as defined by the ICR.

F. Patents, Exclusivities, and Approvals

Patents (Expired and Non-Expired) and Patent Applications

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This table lists each patent that is related to the selected drug, as well as each application for a patent related to the selected drug that is pending with the USPTO.

Patent #	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Patent Application Pending	Patent Type	Listed in FDA Orange Book / Purple Book
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Patent #	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Patent Application Pending	Patent Type	Listed in FDA Orange Book / Purple Book
US 6902734	2001-08-01	2023-09-25	Y	Y	N	N	UTL	Y

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Patent #	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Patent Application Pending	Patent Type	Listed in FDA Orange Book / Purple Book
US 9475858	2012-07-06	2032-07-06	N	N	N	N	UTL	Y
US 8852889	2012-07-06	2032-07-06	N	N	N	N	UTL	Y
US 9217168	2013-03-14	2033-03-14	N	N	N	N	UTL	Y

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Patent #	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Patent Application Pending	Patent Type	Listed in FDA Orange Book / Purple Book
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Explanations: This response, and all accompanying data in Section F, is confidential and proprietary and subject to projections under IRA §1193(c) and FOIA.

Question 12 requests “Patents (Expired and Non-Expired) and Patent Applications,” and we accordingly provided patents and patent applications that have patent claims directed to the selected drug product, selected drug substance, methods of using the selected drug, and/or methods of manufacturing the selected drug. Out of an abundance of caution, we also identified certain manufacturing patents and applications that are included in a broad portfolio license to one or more biosimilar manufacturers, even though this information may not be required by Question 12. These broad portfolio licenses may also include platform device patents (and any related applications) that are not identified in response to Question 12.

The licenses we have granted are the reason biosimilar versions of Stelara® are permitted as of January 2025. For example, Janssen Biotech, Inc. (“Janssen”) and Amgen have reached a settlement agreement that will permit Amgen to launch its biosimilar as of January 1, 2025. Janssen has reached settlement and license agreements with other companies to allow for additional biosimilar versions of Stelara®, [REDACTED]

Question 12 also requests reporting of the “Date Filed.” In response, the date reported for all patents and patent applications is the effective filing date.

Question 12 requests reporting of the “Patent Expiry Date.” In response, the patent expiry date that is listed for the patents includes the 20-year patent term plus any available patent term adjustment (PTA) and/or patent term extension (PTE). For some patents, the expiry date is a result of a terminal disclaimer that was approved by the USPTO. The expiry for the pending applications is listed as “12/31/9999,” because they are pending.

[REDACTED] U.S. 6,902,734 expires September 25, 2023, and is listed in the Purple Book.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

U.S. Pat. Nos. 8,852,889, 9,475,858 [REDACTED] are titled, "Cell Culture Process." U.S. Pat. Nos. 8,852,889 and 9,475,858 are listed in the Purple Book and expire in July 2032.

[REDACTED]

U.S. Pat. Nos. 9,217,168 and 9,663,810 are listed in the Purple Book and expire in March 2033. These patents are titled, “Methods of Cell Culture.”

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

U.S. Pat. No. 10,961,307 [REDACTED] are titled, “Methods of Treating Moderately to Severely Active Ulcerative Colitis by Administering an Anti-IL12/IL23 Antibody.” US 10,961,307 is listed in the Purple Book and expires in September 2039.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

F. Patents, Exclusivities, and Approvals

Regulatory Exclusivity Periods

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. Manufacturers reported all regulatory exclusivity periods under the FD&C Act or the PHS Act that are listed in the Orange Book or the Purple Book and in effect or have expired for the selected drug.

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA/BLA) Number	NDC-9s Covered by Exclusivity
RPE	2021-09-25	125261	57894-0054(IV 130mg/26 mL) 57894-0060 (SC 45mg/0.5mL; single dose vial 45mg/0.5 mL) 57894-0061 (SC 90mg/mL)

Explanations: This response, and all accompanying data in Section F, is confidential and proprietary and subject to projections under IRA §1193(c) and FOIA. Stelara® received its first licensure under 351(a) in the U.S. on September 25, 2009 (as supported by its approval letter for BLA 125261, dated September 25, 2009, and a listing in the current Purple Book). As such, Stelara® was entitled to 12-year Reference Product Exclusivity starting on September 25, 2009. While BLA 761044 was also approved under 351(a), it was not subject to additional or separate product exclusivity, as it was filed for an alternative dosage form and was not associated with any structural changes to the biologic product. In any event, approvals of Stelara® obtained during the 12-year product exclusivity after the first licensure of BLA 125261, are covered by the unexpired Reference Product Exclusivity earned in connection with the first licensure. Finally, please note that consistent with current FDA practice, the end date of exclusivity is not listed/confirmed in the Purple Book. As CMS acknowledges in the ICR, FDA has not made a determination of first licensure for each 351(a) biological product included in the Purple Book, and the absence of a date of first licensure does not mean that a biological product is not, or was not, eligible for Reference Product Exclusivity.

F. Patents, Exclusivities, and Approvals

All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
125261	BLA		2009-09-25	Treatment of adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	45 mg vial 90 mg vial	Janssen Biotech, Inc.	APP	Original Approval/ New molecular Entity. 90 mg vial not launched
125261	BLA		2013-09-20	Treatment of adults with active psoriatic arthritis	45 mg vial 90 mg vial 45 mg PFS 90 mg PFS	Janssen Biotech, Inc.	APP	"PFS" means pre-filled syringe 90mg vial not launched
125261	BLA		2017-10-13	Treatment of patients 12 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	45 mg vial 45 mg PFS 90 mg PFS	Janssen Biotech, Inc.	APP	

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All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
125261	BLA		2020-07-29	Treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	45 mg vial 45 mg PFS 90 mg PFS	Janssen Biotech, Inc.	APP	
125261	BLA		2022-07-29	Treatment of patients 6 years or older with active psoriatic arthritis	45 mg vial 45 mg PFS 90 mg PFS	Janssen Biotech, Inc.	APP	
761044	BLA		2016-09-23	Treatment of adult patients with moderately to severely active Crohn's disease	45 mg vial 45 mg PFS 90 mg PFS 130 mg/26 mL vial for IV infusion	Janssen Biotech, Inc.	APP	
761044	BLA		2019-10-18	Treatment of adult patients with moderately	45 mg vial 45 mg PFS 90 mg PFS 130 mg/26 mL	Janssen Biotech, Inc.	APP	

F. Patents, Exclusivities, and Approvals

All Active and Pending FDA Applications and Approvals

Description: Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. This list contains all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act and 351(a) of the PHS Act.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Class Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
				to severely active ulcerative colitis	vial for IV infusion			

Explanations: None.

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0054-27	2018-Q1		ML	
57894-0054-27	2018-Q2		ML	
57894-0054-27	2018-Q3		ML	
57894-0054-27	2018-Q4		ML	
57894-0054-27	2019-Q1		ML	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0054-27	2019-Q2		ML	
57894-0054-27	2019-Q3		ML	
57894-0054-27	2019-Q4		ML	
57894-0054-27	2020-Q1		ML	
57894-0054-27	2020-Q2		ML	
57894-0054-27	2020-Q3		ML	
57894-0054-27	2020-Q4		ML	
57894-0054-27	2021-Q1		ML	
57894-0054-27	2021-Q2		ML	
57894-0054-27	2021-Q3		ML	
57894-0054-27	2021-Q4		ML	
57894-0054-27	2022-Q1		ML	
57894-0054-27	2022-Q2		ML	
57894-0054-27	2022-Q3		ML	
57894-0054-27	2022-Q4		ML	
57894-0060-02	2018-Q1		ML	
57894-0060-02	2018-Q2		ML	
57894-0060-02	2018-Q3		ML	
57894-0060-02	2018-Q4		ML	
57894-0060-02	2019-Q1		ML	
57894-0060-02	2019-Q2		ML	
57894-0060-02	2019-Q3		ML	

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Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0060-02	2019-Q4		ML	
57894-0060-02	2020-Q1		ML	
57894-0060-02	2020-Q2		ML	
57894-0060-02	2020-Q3		ML	
57894-0060-02	2020-Q4		ML	
57894-0060-02	2021-Q1		ML	
57894-0060-02	2021-Q2		ML	
57894-0060-02	2021-Q3		ML	
57894-0060-02	2021-Q4		ML	
57894-0060-02	2022-Q1		ML	
57894-0060-02	2022-Q2		ML	
57894-0060-02	2022-Q3		ML	
57894-0060-02	2022-Q4		ML	
57894-0060-03	2018-Q1		ML	
57894-0060-03	2018-Q2		ML	
57894-0060-03	2018-Q3		ML	
57894-0060-03	2018-Q4		ML	
57894-0060-03	2019-Q1		ML	
57894-0060-03	2019-Q2		ML	
57894-0060-03	2019-Q3		ML	
57894-0060-03	2019-Q4		ML	
57894-0060-03	2020-Q1		ML	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0060-03	2020-Q2		ML	
57894-0060-03	2020-Q3		ML	
57894-0060-03	2020-Q4		ML	
57894-0060-03	2021-Q1		ML	
57894-0060-03	2021-Q2		ML	
57894-0060-03	2021-Q3		ML	
57894-0060-03	2021-Q4		ML	
57894-0060-03	2022-Q1		ML	
57894-0060-03	2022-Q2		ML	
57894-0060-03	2022-Q3		ML	
57894-0060-03	2022-Q4		ML	
57894-0061-03	2018-Q1		ML	
57894-0061-03	2018-Q2		ML	
57894-0061-03	2018-Q3		ML	
57894-0061-03	2018-Q4		ML	
57894-0061-03	2019-Q1		ML	
57894-0061-03	2019-Q2		ML	
57894-0061-03	2019-Q3		ML	
57894-0061-03	2019-Q4		ML	
57894-0061-03	2020-Q1		ML	
57894-0061-03	2020-Q2		ML	
57894-0061-03	2020-Q3		ML	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0061-03	2020-Q4		ML	
57894-0061-03	2021-Q1		ML	
57894-0061-03	2021-Q2		ML	
57894-0061-03	2021-Q3		ML	
57894-0061-03	2021-Q4		ML	
57894-0061-03	2022-Q1		ML	
57894-0061-03	2022-Q2		ML	
57894-0061-03	2022-Q3		ML	
57894-0061-03	2022-Q4		ML	
57894-0054-16	2018-Q1		ML	
57894-0054-16	2018-Q2		ML	
57894-0054-16	2018-Q3		ML	
57894-0054-16	2018-Q4		ML	
57894-0054-16	2019-Q1		ML	
57894-0054-16	2019-Q2		ML	
57894-0054-16	2019-Q3		ML	
57894-0054-16	2019-Q4		ML	
57894-0054-16	2020-Q1		ML	
57894-0054-16	2020-Q2		ML	
57894-0054-16	2020-Q3		ML	
57894-0054-16	2020-Q4		ML	
57894-0054-16	2021-Q1		ML	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0054-16	2021-Q2		ML	
57894-0054-16	2021-Q3		ML	
57894-0054-16	2021-Q4		ML	
57894-0054-16	2022-Q1		ML	
57894-0054-16	2022-Q2		ML	
57894-0054-16	2022-Q3		ML	
57894-0054-16	2022-Q4		ML	
57894-0060-04	2018-Q1		ML	
57894-0060-04	2018-Q2		ML	
57894-0060-04	2018-Q3		ML	
57894-0060-04	2018-Q4		ML	
57894-0060-04	2019-Q1		ML	
57894-0060-04	2019-Q2		ML	
57894-0060-04	2019-Q3		ML	
57894-0060-04	2019-Q4		ML	
57894-0060-04	2020-Q1		ML	
57894-0060-04	2020-Q2		ML	
57894-0060-04	2020-Q3		ML	
57894-0060-04	2020-Q4		ML	
57894-0060-04	2021-Q1		ML	
57894-0060-04	2021-Q2		ML	
57894-0060-04	2021-Q3		ML	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0060-04	2021-Q4		ML	
57894-0060-04	2022-Q1		ML	
57894-0060-04	2022-Q2		ML	
57894-0060-04	2022-Q3		ML	
57894-0060-04	2022-Q4		ML	
57894-0061-02	2018-Q1		ML	
57894-0061-02	2018-Q2		ML	
57894-0061-02	2018-Q3		ML	
57894-0061-02	2018-Q4		ML	
57894-0061-02	2019-Q1		ML	
57894-0061-02	2019-Q2		ML	
57894-0061-02	2019-Q3		ML	
57894-0061-02	2019-Q4		ML	
57894-0061-02	2020-Q1		ML	
57894-0061-02	2020-Q2		ML	
57894-0061-02	2020-Q3		ML	
57894-0061-02	2020-Q4		ML	
57894-0061-02	2021-Q1		ML	
57894-0061-02	2021-Q2		ML	
57894-0061-02	2021-Q3		ML	
57894-0061-02	2021-Q4		ML	
57894-0061-02	2022-Q1		ML	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0061-02	2022-Q2		ML	
57894-0061-02	2022-Q3		ML	
57894-0061-02	2022-Q4		ML	
57894-0061-04	2018-Q1		ML	
57894-0061-04	2018-Q2		ML	
57894-0061-04	2018-Q3		ML	
57894-0061-04	2018-Q4		ML	
57894-0061-04	2019-Q1		ML	
57894-0061-04	2019-Q2		ML	
57894-0061-04	2019-Q3		ML	
57894-0061-04	2019-Q4		ML	
57894-0061-04	2020-Q1		ML	
57894-0061-04	2020-Q2		ML	
57894-0061-04	2020-Q3		ML	
57894-0061-04	2020-Q4		ML	
57894-0061-04	2021-Q1		ML	
57894-0061-04	2021-Q2		ML	
57894-0061-04	2021-Q3		ML	
57894-0061-04	2021-Q4		ML	
57894-0061-04	2022-Q1		ML	
57894-0061-04	2022-Q2		ML	
57894-0061-04	2022-Q3		ML	

G. Market Data and Revenue and Sales Volume Data

Wholesale Acquisition Cost Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Wholesale Acquisition Cost (WAC) unit price of the selected drug.

National Drug Code (NDC-11)	Quarter	WAC	Unit type (each, ML, GM)	Total Unit Volume
57894-0061-04	2022-Q4		ML	

Explanations: Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. Eight NDC-11s for “STELARA” are included in the “Selected Drug List for Initial Price Applicability Year (IPAY) 2026”. All eight NDC-11s are included in this submission.

Four NDC-11s with total package unit volume “0” were “not marketed, sold, or distributed”. For purposes of instructional compliance, rows were added to – “enter “0” in the total unit volume field and left blank for other calculated fields. These four NDCs are:

Three NDC-11s are sample NDCs under Janssen Biotech, Inc. (“JBI”) labeler 57894: 57894-0060-04, 57894-0061-04, 57894-0054-16; Rows were added to – “enter “0” in the total unit volume field and left blank for other calculated fields.

One NDC-11 (57894-0061-02) under JBI labeler 57894 is an inactive NDC. This NDC had a market end date of September 30, 2009 on the DailyMed website. This NDC-11 did not have sales and is not listed on the FDA website.

The WAC and units reported are per ML (labeled per NDC).

Units = gross trade product sales units only, which excludes product returns.

Quarters tie to our J&J financial calendar (e.g., Q1 2023 is the 12 week period January 2, 2023 through April 2, 2023). Most recent 5 years utilized for analysis was FY 2018 through FY 2022. Based on US data only.

G. Market Data and Revenue and Sales Volume Data					
Medicaid Best Price					
Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Medicaid best price of the selected drug. The Medicaid best price information reflects what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – determination of best price.					
Medicaid Best Price	National Drug Code (NDC-9)	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
Y	57894-0054	2018-Q1		ML	
Y	57894-0060	2018-Q1		ML	
Y	57894-0061	2018-Q1		ML	
Y	57894-0054	2018-Q2		ML	
Y	57894-0060	2018-Q2		ML	
Y	57894-0061	2018-Q2		ML	
Y	57894-0054	2018-Q3		ML	
Y	57894-0060	2018-Q3		ML	
Y	57894-0061	2018-Q3		ML	
Y	57894-0054	2018-Q4		ML	
Y	57894-0060	2018-Q4		ML	
Y	57894-0061	2018-Q4		ML	
Y	57894-0054	2019-Q1		ML	
Y	57894-0060	2019-Q1		ML	

G. Market Data and Revenue and Sales Volume Data

Medicaid Best Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Medicaid best price of the selected drug. The Medicaid best price information reflects what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – determination of best price.

Medicaid Best Price	National Drug Code (NDC-9)	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
Y	57894-0061	2019-Q1		ML	
Y	57894-0054	2019-Q2		ML	
Y	57894-0060	2019-Q2		ML	
Y	57894-0061	2019-Q2		ML	
Y	57894-0054	2019-Q3		ML	
Y	57894-0060	2019-Q3		ML	
Y	57894-0061	2019-Q3		ML	
Y	57894-0054	2019-Q4		ML	
Y	57894-0060	2019-Q4		ML	
Y	57894-0061	2019-Q4		ML	
Y	57894-0054	2020-Q1		ML	
Y	57894-0060	2020-Q1		ML	
Y	57894-0061	2020-Q1		ML	
Y	57894-0054	2020-Q2		ML	
Y	57894-0060	2020-Q2		ML	
Y	57894-0061	2020-Q2		ML	
Y	57894-0054	2020-Q3		ML	
Y	57894-0060	2020-Q3		ML	
Y	57894-0061	2020-Q3		ML	
Y	57894-0054	2020-Q4		ML	

G. Market Data and Revenue and Sales Volume Data

Medicaid Best Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Medicaid best price of the selected drug. The Medicaid best price information reflects what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – determination of best price.

Medicaid Best Price	National Drug Code (NDC-9)	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
Y	57894-0060	2020-Q4		ML	
Y	57894-0061	2020-Q4		ML	
Y	57894-0054	2021-Q1		ML	
Y	57894-0060	2021-Q1		ML	
Y	57894-0061	2021-Q1		ML	
Y	57894-0054	2021-Q2		ML	
Y	57894-0060	2021-Q2		ML	
Y	57894-0061	2021-Q2		ML	
Y	57894-0054	2021-Q3		ML	
Y	57894-0060	2021-Q3		ML	
Y	57894-0061	2021-Q3		ML	
Y	57894-0054	2021-Q4		ML	
Y	57894-0060	2021-Q4		ML	
Y	57894-0061	2021-Q4		ML	
Y	57894-0054	2022-Q1		ML	
Y	57894-0060	2022-Q1		ML	
Y	57894-0061	2022-Q1		ML	
Y	57894-0054	2022-Q2		ML	
Y	57894-0060	2022-Q2		ML	
Y	57894-0061	2022-Q2		ML	

G. Market Data and Revenue and Sales Volume Data**Medicaid Best Price**

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Medicaid best price of the selected drug. The Medicaid best price information reflects what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – determination of best price.

Medicaid Best Price	National Drug Code (NDC-9)	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
Y	57894-0054	2022-Q3		ML	
Y	57894-0060	2022-Q3		ML	
Y	57894-0061	2022-Q3		ML	
Y	57894-0054	2022-Q4		ML	
Y	57894-0060	2022-Q4		ML	
Y	57894-0061	2022-Q4		ML	

Explanations: Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. Three NDC-9s for “STELARA” are included in the “Selected Drug List for Initial Price Applicability Year (IPAY) 2026”.

All Three NDC-9s are included from Janssen Biotech, Inc. (“JBI”) 57894 labeler, the “Primary Manufacturer”, as defined by the IRA ICR Final Guidance August 3, 2023.

The “most recent five years” is assumed to be 2018-2022 and the quarters within the five-year period are 1Q2018-4Q2022.

“Medicaid Best Price” (BP) information reflects BP at the NDC-9 level and reflects the lowest unit of measure by Medicaid unit type as submitted under the Medicaid Drug Rebate Program (MDRP) and reflects any restatements at the point in time of submission per the requirements under the ICR.

The submission has been modified to accommodate system limitations in HPMS. ""The Medicaid best price information must reflect what was submitted to Medicaid under the MDRP"" and is submitted under the MDRP out to six decimal places. The IRA ICR format permits reporting only to two decimal places and HPMS does not allow the user to move forward in the system unless information is submitted in the format

available. To address the inconsistencies between MDRP and HPMS, the primary manufacturer reported Best Price at the lowest unit of measure rounded to the closest two decimals.

The submitted quarterly Average Manufacturer Price (AMP) unit volume is the sum of monthly AMP units within the quarter as reported under the MDRP government price reporting regulation and Medicaid Drug Program (MDP) system user guidance. AMP unit volume reflects the lowest unit of measure by Medicaid unit type to match ICR requirements. AMP units are not required as part of Best Price reporting under the MDRP.

G. Market Data and Revenue and Sales Volume Data					
Federal Supply Schedule Price					
Description: : The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.					
Federal Supply Schedule Price	National Drug Code(NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0054-27	2018-01-01 - 2018-12-31	\$1,511.56	ML	
Y	57894-0060-02	2018-01-01 - 2018-12-31	\$6,402.16	ML	
Y	57894-0060-03	2018-01-01 - 2018-12-31	\$5,639.91	ML	
Y	57894-0061-03	2018-01-01 - 2018-12-31	\$9,909.35	ML	
Y	57894-0054-27	2019-01-01 - 2019-08-31	\$1,511.56	ML	
Y	57894-0054-27	2019-09-01 - 2019-09-30	\$1,575.88	ML	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: : The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code(NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0054-27	2019-10-01 - 2019-12-31	\$1,497.09	ML	
Y	57894-0060-02	2019-01-01 - 2019-08-31	\$6,907.93	ML	
Y	57894-0060-02	2019-09-01 - 2019-12-31	\$10,725.87	ML	
Y	57894-0060-03	2019-01-01 - 2019-08-31	\$6,253.38	ML	
Y	57894-0060-03	2019-09-01 - 2019-09-30	\$6,464.91	ML	
Y	57894-0060-03	2019-10-01 - 2019-12-31	\$6,192.25	ML	
Y	57894-0061-03	2019-01-01 - 2019-08-31	\$10,987.26	ML	
Y	57894-0061-03	2019-09-01 - 2019-09-30	\$12,929.79	ML	
Y	57894-0061-03	2019-10-01 - 2019-12-31	\$12,384.50	ML	
Y	57894-0054-27	2020-01-01 - 2020-12-31	\$1,497.09	ML	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: : The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code(NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0060-02	2020-01-01 - 2020-12-31	\$10,725.87	ML	
Y	57894-0060-03	2020-01-01 - 2020-12-31	\$6,192.25	ML	
Y	57894-0061-03	2020-01-01 - 2020-12-31	\$12,384.50	ML	
Y	57894-0054-27	2021-01-01 - 2021-12-31	\$1,517.60	ML	
Y	57894-0060-02	2021-01-01 - 2021-12-31	\$10,872.81	ML	
Y	57894-0060-03	2021-01-01 - 2021-12-31	\$6,277.09	ML	
Y	57894-0061-03	2021-01-01 - 2021-12-31	\$12,554.17	ML	
Y	57894-0054-27	2022-01-01 - 2022-12-31	\$1,590.44	ML	
Y	57894-0060-02	2022-01-01 - 2022-12-31	\$11,394.71	ML	
Y	57894-0060-03	2022-01-01 - 2022-12-31	\$6,578.38	ML	

G. Market Data and Revenue and Sales Volume Data

Federal Supply Schedule Price

Description: : The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. Manufacturers reported any federal supply schedule (FSS) price for the selected drug made available during the most recent five years. The FSS price information reflects what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Federal Supply Schedule Price	National Drug Code(NDC-11)	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0061-03	2022-01-01 - 2022-12-31	\$13,156.77	ML	

Explanations: Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. Eight NDC-11s for “STELARA” are included in the “Selected Drug List for Initial Price Applicability Year (IPAY) 2026”. Not all Eight NDC-11s are included in this submission.

Four NDC-11s are excluded from submission because Federal Supply Schedule (FSS) prices for these NDCs are not included in FSS contracts with Janssen Biotech, Inc. (“JBI”) and not listed on the VA National Acquisition Center (VA NAC) website.

Three NDC-11s are sample NDCs under JBI labeler 57894 NDCs: 57894-0060-04, 57894-0061-04, 57894-0054-16.

One NDC-11 (57894-0061-02) under JBI labeler 57894 is an inactive NDC. This NDC had a market end date of September 30, 2009 on the DailyMed website. This NDC-11 did not have sales and is not listed on the FDA website. Therefore, it was never added to an FSS contract.

Four NDC-11s are included in the FSS price submission under the JBI labeler 57894.

“Federal Supply Schedule Price”: for NDC-11 (57894-0054-27), a start date difference was identified between the contract modification received by JBI (October, 1, 2019) and the information reported on the VA NAC website (October 3, 2019). Data in this submission is based on the documentation received by JBI confirming the start date of October 1, 2019.

“Federal Supply Schedule Price” reflects those that can be found online in the Pharmaceutical pricing data for all VA NAC Programs by NDC-11 to match ICR requirements. In order to reconcile to the VA NAC, the pricing submitted includes IFF. Note, the ICR requests a data point “Federal

Supply Schedule Service Price” which we are unfamiliar with and are not reporting. In its place we are reporting the “Federal Supply Schedule Price”.

“FSS Total Unit Volume” captures unit quantity at the package level used to calculate the FSS price in accordance with the Veteran’s Health Care Act (VHCA) public law.

ICR required reporting total unit volume sold to "direct federal purchasers".

For purposes of this submission, the 2018-2022 invoice data was pulled at a point in time in August 2023. It is our assumption that for this request, CMS intends to correlate the reported FSS price to the units sold during the time period that price was in effect.

G. Market Data and Revenue and Sales Volume Data					
Big Four Price					
Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.					
Big Four Price	National Drug Code(NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0054-27	2018-01-01 - 2018-12-31	\$1,197.51	ML	
Y	57894-0060-02	2018-01-01 - 2018-12-31	\$6,065.33	ML	
Y	57894-0060-03	2018-01-01 - 2018-12-31	\$5,639.91	ML	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code(NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0061-03	2018-01-01 - 2018-12-31	\$9,909.35	ML	
Y	57894-0054-27	2019-01-01 - 2019-08-31	\$1,147.43	ML	
Y	57894-0054-27	2019-09-01 - 2019-12-31	\$1,147.43	ML	
Y	57894-0060-02	2019-01-01 - 2019-08-31	\$5,663.05	ML	
Y	57894-0060-02	2019-09-01 - 2019-12-31	\$5,663.05	ML	
Y	57894-0060-03	2019-01-01 - 2019-08-31	\$5,844.28	ML	
Y	57894-0060-03	2019-09-01 - 2019-09-30	\$6,464.91	ML	
Y	57894-0060-03	2019-10-01 - 2019-12-31	\$6,192.25	ML	
Y	57894-0061-03	2019-01-01 - 2019-08-31	\$10,987.26	ML	
Y	57894-0061-03	2019-09-01 - 2019-09-30	\$12,929.79	ML	
Y	57894-0061-03	2019-10-01 - 2019-12-31	\$12,384.50	ML	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code(NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0054-27	2020-01-01 - 2020-12-31	\$1,153.92	ML	
Y	57894-0060-02	2020-01-01 - 2020-12-31	\$6,176.54	ML	
Y	57894-0060-03	2020-01-01 - 2020-12-31	\$6,192.25	ML	
Y	57894-0061-03	2020-01-01 - 2020-12-31	\$12,384.50	ML	
Y	57894-0054-27	2021-01-01 - 2021-12-31	\$1,137.06	ML	
Y	57894-0060-02	2021-01-01 - 2021-12-31	\$6,249.98	ML	
Y	57894-0060-03	2021-01-01 - 2021-12-31	\$6,277.09	ML	
Y	57894-0061-03	2021-01-01 - 2021-12-31	\$12,554.17	ML	
Y	57894-0054-27	2022-01-01 - 2022-12-31	\$1,125.70	ML	
Y	57894-0060-02	2022-01-01 - 2022-12-31	\$5,913.19	ML	
Y	57894-0060-03	2022-01-01 - 2022-12-31	\$6,578.38	ML	

G. Market Data and Revenue and Sales Volume Data

Big Four Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides responses about the Big Four price of the selected drug. The Big Four price information reflects the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.

Big Four Price	National Drug Code(NDC-11)	Price Start Date to End Date	Big Four Price	Unit Type (EA, ML, GM)	Total Unit Volume
Y	57894-0061-03	2022-01-01 - 2022-12-31	\$13,156.77	ML	

Explanations: Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA. Eight NDC-11s for “STELARA” are included in the “Selected Drug List for Initial Price Applicability Year (IPAY) 2026”. Not all Eight NDC-11s are included in this submission.

Four NDC-11s are excluded from submission because Big Four prices for these NDCs are not included in FSS contracts with Janssen Biotech, Inc. (“JBI”) and are not listed on the VA National Acquisition Center (“VA NAC”) website.

Three NDC-11 are sample NDCs under JBI labeler 57894 NDCs: 57894-0060-04, 57894-0061-04, 57894-0054-16.

One NDC-11 (57894-0061-02) under JBI labeler 57894 is an inactive NDC. This NDC had a market end date of September 30, 2009 on the DailyMed website. This NDC-11 did not have sales and is not listed on the FDA website. Therefore, it was never added to an FSS contract.

Four NDC-11s are included in Big Four information submission under the JBI labeler 57894.

“Big Four Price” prices reflect those that can be found online in the Pharmaceutical pricing data for all VA NAC Programs by NDC-11 to match ICR requirements. In order to reconcile to the VA NAC, the pricing submitted includes IFF.

“Big Four Total Unit Volume” is the total number of units for each NDC-11 sold to the Big Four federal agencies and could include units sold with prices that reflect temporary price reduction and/or uniform formulary blanket purchase agreement price.

The reported total unit volume captures unit quantity at the package level used to calculate the Big Four price in accordance with the Veteran’s Health Care Act (VHCA) public law.

For purposes of this submission, the 2018-2022 invoice data was pulled at a point in time in August 2023. It is our assumption that for this request, CMS intends to correlate the reported Big Four price to the units sold during the time period that price was in effect.

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0054-27	2018-Q1				ML	
57894-0054-27	2018-Q2				ML	
57894-0054-27	2018-Q3				ML	
57894-0054-27	2018-Q4				ML	
57894-0054-27	2019-Q1				ML	
57894-0054-27	2019-Q2				ML	
57894-0054-27	2019-Q3				ML	
57894-0054-27	2019-Q4				ML	
57894-0054-27	2020-Q1				ML	
57894-0054-27	2020-Q2				ML	
57894-0054-27	2020-Q3				ML	
57894-0054-27	2020-Q4				ML	
57894-0054-27	2021-Q1				ML	
57894-0054-27	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0054-27	2021-Q3				ML	
57894-0054-27	2021-Q4				ML	
57894-0054-27	2022-Q1				ML	
57894-0054-27	2022-Q2				ML	
57894-0054-27	2022-Q3				ML	
57894-0054-27	2022-Q4				ML	
57894-0060-02	2018-Q1				ML	
57894-0060-02	2018-Q2				ML	
57894-0060-02	2018-Q3				ML	
57894-0060-02	2018-Q4				ML	
57894-0060-02	2019-Q1				ML	
57894-0060-02	2019-Q2				ML	
57894-0060-02	2019-Q3				ML	
57894-0060-02	2019-Q4				ML	
57894-0060-02	2020-Q1				ML	
57894-0060-02	2020-Q2				ML	
57894-0060-02	2020-Q3				ML	
57894-0060-02	2020-Q4				ML	
57894-0060-02	2021-Q1				ML	
57894-0060-02	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0060-02	2021-Q3				ML	
57894-0060-02	2021-Q4				ML	
57894-0060-02	2022-Q1				ML	
57894-0060-02	2022-Q2				ML	
57894-0060-02	2022-Q3				ML	
57894-0060-02	2022-Q4				ML	
57894-0060-03	2018-Q1				ML	
57894-0060-03	2018-Q2				ML	
57894-0060-03	2018-Q3				ML	
57894-0060-03	2018-Q4				ML	
57894-0060-03	2019-Q1				ML	
57894-0060-03	2019-Q2				ML	
57894-0060-03	2019-Q3				ML	
57894-0060-03	2019-Q4				ML	
57894-0060-03	2020-Q1				ML	
57894-0060-03	2020-Q2				ML	
57894-0060-03	2020-Q3				ML	
57894-0060-03	2020-Q4				ML	
57894-0060-03	2021-Q1				ML	
57894-0060-03	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0060-03	2021-Q3				ML	
57894-0060-03	2021-Q4				ML	
57894-0060-03	2022-Q1				ML	
57894-0060-03	2022-Q3				ML	
57894-0060-03	2022-Q3				ML	
57894-0060-03	2022-Q4				ML	
57894-0061-03	2018-Q1				ML	
57894-0061-03	2018-Q2				ML	
57894-0061-03	2018-Q3				ML	
57894-0061-03	2018-Q4				ML	
57894-0061-03	2019-Q1				ML	
57894-0061-03	2019-Q2				ML	
57894-0061-03	2019-Q3				ML	
57894-0061-03	2019-Q4				ML	
57894-0061-03	2020-Q1				ML	
57894-0061-03	2020-Q2				ML	
57894-0061-03	2020-Q3				ML	
57894-0061-03	2020-Q4				ML	
57894-0061-03	2021-Q1				ML	
57894-0061-03	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0061-03	2021-Q3				ML	
57894-0061-03	2021-Q4				ML	
57894-0061-03	2022-Q1				ML	
57894-0061-03	2022-Q2				ML	
57894-0061-03	2022-Q3				ML	
57894-0061-03	2022-Q4				ML	
57894-0054-16	2018-Q1				ML	
57894-0054-16	2018-Q2				ML	
57894-0054-16	2018-Q3				ML	
57894-0054-16	2018-Q4				ML	
57894-0054-16	2019-Q1				ML	
57894-0054-16	2019-Q2				ML	
57894-0054-16	2019-Q3				ML	
57894-0054-16	2019-Q4				ML	
57894-0054-16	2020-Q1				ML	
57894-0054-16	2020-Q2				ML	
57894-0054-16	2020-Q3				ML	
57894-0054-16	2020-Q4				ML	
57894-0054-16	2021-Q1				ML	
57894-0054-16	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0054-16	2021-Q3				ML	
57894-0054-16	2021-Q4				ML	
57894-0054-16	2022-Q1				ML	
57894-0054-16	2022-Q2				ML	
57894-0054-16	2022-Q3				ML	
57894-0054-16	2022-Q4				ML	
57894-0060-04	2018-Q1				ML	
57894-0060-04	2018-Q2				ML	
57894-0060-04	2018-Q3				ML	
57894-0060-04	2018-Q4				ML	
57894-0060-04	2019-Q1				ML	
57894-0060-04	2019-Q2				ML	
57894-0060-04	2019-Q3				ML	
57894-0060-04	2019-Q4				ML	
57894-0060-04	2020-Q1				ML	
57894-0060-04	2020-Q2				ML	
57894-0060-04	2020-Q3				ML	
57894-0060-04	2020-Q4				ML	
57894-0060-04	2021-Q1				ML	
57894-0060-04	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0060-04	2021-Q3				ML	
57894-0060-04	2021-Q4				ML	
57894-0060-04	2022-Q1				ML	
57894-0060-04	2022-Q2				ML	
57894-0060-04	2022-Q3				ML	
57894-0060-04	2022-Q4				ML	
57894-0061-02	2018-Q1				ML	
57894-0061-02	2018-Q2				ML	
57894-0061-02	2018-Q3				ML	
57894-0061-02	2018-Q4				ML	
57894-0061-02	2019-Q1				ML	
57894-0061-02	2019-Q2				ML	
57894-0061-02	2019-Q3				ML	
57894-0061-02	2019-Q4				ML	
57894-0061-02	2020-Q1				ML	
57894-0061-02	2020-Q2				ML	
57894-0061-02	2020-Q3				ML	
57894-0061-02	2020-Q4				ML	
57894-0061-02	2021-Q1				ML	
57894-0061-02	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0061-02	2021-Q3				ML	
57894-0061-02	2021-Q4				ML	
57894-0061-02	2022-Q1				ML	
57894-0061-02	2022-Q2				ML	
57894-0061-02	2022-Q3				ML	
57894-0061-02	2022-Q4				ML	
57894-0061-04	2018-Q1				ML	
57894-0061-04	2018-Q2				ML	
57894-0061-04	2018-Q3				ML	
57894-0061-04	2018-Q4				ML	
57894-0061-04	2019-Q1				ML	
57894-0061-04	2019-Q2				ML	
57894-0061-04	2019-Q3				ML	
57894-0061-04	2019-Q4				ML	
57894-0061-04	2020-Q1				ML	
57894-0061-04	2020-Q2				ML	
57894-0061-04	2020-Q3				ML	
57894-0061-04	2020-Q4				ML	
57894-0061-04	2021-Q1				ML	
57894-0061-04	2021-Q2				ML	

G. Market Data and Revenue and Sales Volume Data

U.S. Commercial Average Net Unit Price

Description: The purpose of this section is to collect the market data, revenue and sales volume data described in section 1194(e)(1)(E) of the Act. The following table provides the U.S. commercial average net unit price, including group and individual commercial plans on- and off-exchange of the selected drug.

National Drug Code (NDC-11)	Quarter	U.S. Commercial Average Unit Net Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (EA, ML, GM)	Total Unit Volume
57894-0061-04	2021-Q3				ML	
57894-0061-04	2021-Q4				ML	
57894-0061-04	2022-Q1				ML	
57894-0061-04	2022-Q2				ML	
57894-0061-04	2022-Q3				ML	
57894-0061-04	2022-Q4				ML	

Explanations: Confidential & Proprietary, Subject to Protections Under IRA §1193(c) and FOIA

Eight NDC-11s for “STELARA” are included in the “Selected Drug List for Initial Price Applicability Year (IPAY) 2026”. All eight NDC-11s are included in this submission.

Four NDC-11s with total package unit volume “0” were “not marketed, sold, or distributed”. For purposes of instructional compliance, rows were added to – “enter “0” in the total unit volume field and left blank for other calculated fields. These four NDCs are:

Three NDC-11s are sample NDCs under Janssen Biotech, Inc. (“JBI”) labeler 57894: 57894-0060-04, 57894-0061-04, 57894-0054-16; Rows were added to – “enter “0” in the total unit volume field and left blank for other calculated fields.

One NDC-11 (57894-0061-02) under JBI labeler 57894 is an inactive NDC. This NDC had a market end date of September 30, 2009 on the DailyMed website. This NDC-11 did not have sales and is not listed on the FDA website.



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Based on US data only.

Manufacturer E2 Submission – Johnson & Johnson Health Care Systems



Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Respondent Name	Laura D'Meza
	Organization Name (if applicable)	Johnson & Johnson Health Care Systems
	Respondent Email	ldmeza@its.jnj.com
	Who is completing this form?	
Question 27: Prescribing Information	Prescribing Information	<p>Section I (Question 27 through 30 and 32) is confidential & proprietary, use subject to IRA 1193(c); FOIA exemptions apply NOTE: Please review the executive summary prior to this section</p> <p>STELARA® (ustekinumab) is the only IL-12/23 inhibitor in the US market and is approved for moderate-to-severe Crohn's Disease (CD), moderate-to-severe Ulcerative Colitis (UC), moderate-to-severe Plaque Psoriasis (PsO), and active Psoriatic Arthritis (PsA). Medicare beneficiaries need safe, effective options to treat these chronic, extremely debilitating, and distressing immune-related diseases. [1–3]</p> <p>Treatments for CD/UC/PsO/PsA include two classes of biologics (defined by FDA's formulary drug classification): Tumor Necrosis Factor (TNF)-inhibitors and non-TNF-inhibitors, as well as non-biologic treatments such as corticosteroids and immunomodulators.[4]</p> <p>SKYRIZI® AND ENTYVIO® ARE THE THERAPEUTIC ALTERNATIVES TO STELARA®. (see Table 3 in Question 28)</p> <p>Per the Information Collection Request Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act, "CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or MOA before considering therapeutic alternatives in other drug classes." [5]</p> <p>Therapeutic Alternative in CD/PsO/PsA: SKYRIZI® (risankizumab) is the market-leading interleukin-23 (IL-23), with the most overlapping indications (CD/PsO/PsA) to STELARA® (the only IL-12/23 inhibitor) and meets all three of CMS' properties for determining a therapeutic alternative: chemical class (non-TNF-inhibitor), therapeutic class (biologic) and mechanism of action (IL-23). [4]</p>



Question	Sub-Question	Response
		<p>Like STELARA®, SKYRIZI® is used in both patients who are new to biologics and more commonly for those who have received prior biologic treatment but did not have an adequate response. [6,7]</p> <p>Therapeutic Alternative in UC: ENTYVIO® (vedolizumab) is the therapeutic alternative to STELARA® in UC. ENTYVIO® (a gut-selective integrin receptor antagonist) is the only treatment that meets two of the three CMS properties for determining the therapeutic alternative for STELARA®: chemical class (non-TNF-inhibitor), and therapeutic class (biologic). In addition, STELARA® and ENTYVIO® are the only treatments in the non-TNF-inhibitor class of drugs that are FDA approved for UC (SKYRIZI® has filed for UC with the FDA).</p> <p>TNF-inhibitors are not an appropriate therapeutic alternative since STELARA® represents a significant therapeutic advance to this class of biologics.</p> <p>STELARA® has four indications (two in patients aged 18 and older, and two in patients aged six and older).</p> <p>STELARA® Indication #1: Treatment of adult patients with moderately to severely active Crohn’s Disease</p> <p>STELARA® Use in Course of Care: The recommended dose of STELARA® is a single intravenous (IV) infusion starter dose of 260 mg (patients 55 kg or less), 390mg (>55 kg to 85 kg), or 520 mg (>85 kg), followed by a dosage of 90 mg subcutaneously administered 8 weeks after the initial IV dose, then every 8 weeks thereafter. STELARA® does not require monitoring for liver toxicity.</p> <p>SKYRIZI® Use in Course of Care: Prior to initiating treatment with SKYRIZI®, liver enzymes and bilirubin levels need to be obtained. The recommended dose of SKYRIZI® is an IV infusion induction dose of 600 mg at week 0, week 4 and week 8, followed by a dosage of 180 mg or 360 mg subcutaneously (injection under skin) administered at week 12, and every 8 weeks thereafter.</p> <p>STELARA® Indication #2: Treatment of adult patients with moderately to severely active Ulcerative Colitis</p> <p>STELARA® Use in Course of Care: The recommended dose of STELARA® is a single IV infusion starter dose of 260 mg (patients 55 kg or less), 390mg (>55 kg to 85 kg), or 520 mg (>85 kg), followed by a maintenance dosage of 90 mg subcutaneously administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.</p> <p>ENTYVIO® Use in Course of Care: The recommended dose of ENTYVIO® is 300 mg administered by IV infusion at 0, 2 and 6 weeks, and then every 8 weeks thereafter. The recommended subcutaneous dose is 108 mg every 2 weeks, after two 300 mg IV starter doses.</p>



Question	Sub-Question	Response
		<p>STELARA® Indication #3: Treatment of patients six years or older with moderate to severe Plaque PsO who are candidates for phototherapy or systemic therapy.</p> <p>STELARA® Use in Course of Care: The recommended dose for adults weighing ≤100 kg is 45 mg initially and 4 weeks later, followed by 45mg every 12 weeks. For adults >100kg, the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. For pediatric patients weighing <60kg, the recommended dose is 0.75 mg/kg at weeks 0 and 4, then every 12 weeks thereafter. For pediatric patients weighing 60kg-100kg, the recommended dose is 45 mg at weeks 0 and 4, then every 12 weeks thereafter. For pediatric patients weighing >100 kg, the recommended dose is 90 mg at weeks 0 and 4, then every 12 weeks thereafter.</p> <p>SKYRIZI® Use in Course of Care: The recommended dose for adults is 150 mg administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter. SKYRIZI® is not approved for pediatric patients with moderate to severe plaque psoriasis.</p> <p>STELARA® Indication #4: Treatment of patients six years or older with active Psoriatic Arthritis.</p> <p>STELARA® Use in Course of Care: The recommended adult dosage is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. For patients with co-existent moderate to severe plaque psoriasis weighing >100 kg, the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. For pediatric patients weighing <60kg, the recommended dose is 0.75 mg/kg at weeks 0 and 4, then every 12 weeks thereafter. For pediatric patients weighing 60 kg or more, the recommended dose is 45 mg at weeks 0 and 4, then every 12 weeks thereafter. For pediatric patients weighing >100 kg with co-existent moderate to severe plaque psoriasis, the recommended dose is 90 mg at weeks 0 and 4, then every 12 weeks thereafter.</p> <p>SKYRIZI® Use in Course of Care: The recommended dose for adults is 150 mg administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter. SKYRIZI® may be administered alone or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs). SKYRIZI® is not approved for pediatric patients with active psoriatic arthritis.</p> <p>SAFETY INFORMATION IS SIMILAR FOR STELARA®, SKYRIZI®, AND ENTYVIO®.</p> <p>Most warnings and precautions are similar across STELARA® and its therapeutic alternatives, including potential hypersensitivity, increased risk of infection, and risk of tuberculosis; none of which are boxed warnings.</p>



Question	Sub-Question	Response
		<p>SKYRIZI® has an additional warning for potential damage to the liver (hepatotoxicity) in the treatment of CD.</p> <p>ENTYVIO® has a warning/precaution for progressive multifocal leukoencephalopathy (PML), a rare serious brain infection caused by a virus resulting in severe brain damage and often death.</p> <p>STELARA® has an additional warning/precaution for cancer, as well as a brain disorder in which a person may experience vision disturbances, seizures, headaches, and altered mental status (posterior reversible encephalopathy syndrome [PRES]).</p> <p>ADMINISTRATION AND STORAGE INFORMATION VARIES FOR STELARA®, SKYRIZI®, AND ENTYVIO®.</p> <p>STELARA®, SKYRIZI®, and ENTYVIO® are subcutaneous injections and IV infusions. The IV infusions require health care provider (HCP) administration, while the maintenance doses are either IV infusion (ENTYVIO® only) or self-administered via subcutaneous injection across indications.</p> <p>STELARA® prefilled syringes may be stored at room temperature for up to 30 days.</p> <p>SKYRIZI® prefilled syringes require refrigeration.</p> <p>ENTYVIO® maintenance therapy is available as an IV infusion, and subcutaneous injection. Unopened vials of ENTYVIO® require refrigeration. Prefilled syringes or pens can be left at room temperature for up to 7 days.</p> <p>TREATMENT GUIDELINES ENDORSE THE USE OF STELARA® FOR ITS APPROVED INDICATIONS.</p> <p>Biologics are guideline-recommended treatment options for moderate-to-severe CD, UC, PsO and active PsA.</p> <p>CD: The American College of Gastroenterology (ACG) [8] and American Gastroenterological Association (AGA)[9] *Recommend STELARA® for treatment of moderate-to-severe Crohn’s Disease in patients who have failed previous therapies including oral agents or TNF-inhibitors, or in patients who have had no previous exposure to TNF-inhibitors</p> <p>UC: American Gastroenterological Association (AGA) [10] *Recommends STELARA® for treatment of moderate-to-severe UC *Suggests STELARA®, rather than ENTYVIO®, in patients who did not respond to infliximab (TNF-inhibitor) to induce</p>



Question	Sub-Question	Response
		<p>remission</p> <p>PsO: Joint American Academy of Dermatology-National Psoriasis Foundation (AAD-NPF) *Recommends STELARA® for the treatment of moderate-to-severe PsO as a monotherapy for use in adult patients. The AAD-NPF specifically notes that STELARA® is also recommended as a monotherapy for difficult to treat areas of psoriasis including nails, scalp, palms, and soles [11] *Recommends STELARA® for the treatment of PsO of any severity when associated with PsA as a monotherapy treatment option for use in adult patients [11] *Recommends STELARA® for the treatment of moderate-to-severe PsO as an effective therapy for adolescents 12 years and older. Pediatric guidelines were written prior to FDA approval in patients aged 6-11 [12]</p> <p>PsA: The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) guidelines *Strongly recommends STELARA® for use in patients with active PsA who also have CD or UC [13]</p> <p>CONCLUSION:</p> <p>There is no other biologic on the market today in the IL-12/23 class, a mechanism of action unique to STELARA®. Per CMS guidance, the therapeutic alternative for STELARA® in CD, PsO and PsA is SKYRIZI® and for UC, it is ENTYVIO®.</p> <p>TNF-Inhibitors are not appropriate therapeutic alternatives to STELARA®, due to significantly improved safety profile (no boxed warning), lower immunogenicity vs. most TNF-inhibitors, improvement in persistency in CD, UC, PsA, and superior efficacy in PsO (vs. ENBREL®).</p> <p>STELARA® provides long-term safety, efficacy and effectiveness across CD, UC, PsO, and PsA. STELARA® is an important therapeutic option for Medicare beneficiaries suffering from these chronic, disabling conditions, [REDACTED]</p> <p>[REDACTED]</p> <p>References</p> <p>[1] Berre CL, Honap S, Peyrin-Biroulet L. Ulcerative colitis. Lancet. 2023;402:571–584. [2] IBS vs IBD [Internet]. Available from: https://www.crohnscolitisfoundation.org/what-is-ibd/ibs-vs-ibd. [3] Grozdev IS, Voorhees ASV, Gottlieb AB, et al. Psoriasis in the elderly: From the Medical Board of the National</p>



Question	Sub-Question	Response
		<p>Psoriasis Foundation. J Am Acad Dermatol. 2011;65:537–545.</p> <p>[4] Administration UF& D. USP Therapeutic Categories Model Guidelines [Internet]. Available from: https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines.</p> <p>[5] Department of Health and Human Services. Centers for Medicare and Medicaid Services. Information Collection Request Form for Negotiation Data Elements Under Section 11001 and 11002 of Inflation Reduction Act (CMS-10847, OMB 0938-NEW) [Internet]. Available from: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.</p> <p>[6] USPI. STELARA (ustekinumab) [Internet]. Janssen Biotech, Inc.; Available from: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf.</p> <p>[7] SKYRIZI (risankizumab) [Internet]. AbbVie Inc.; Available from: https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.</p> <p>[8] Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn’s Disease in Adults. Am J Gastroenterol. 2018;113:481–517.</p> <p>[9] Feuerstein J, Ho E, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn’s disease [Internet]. p. 2496–2508. Available from: https://www.gastrojournal.org/article/S0016-5085(21)00645-4/fulltext.</p> <p>[10] Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158:1450–1461.</p> <p>[11] Menter A, Strober B, Kaplan D, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029–1072.</p> <p>[12] Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol. 2020;82:161–201.</p> <p>[13] Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol. 2022;18:465–479.</p>
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and	Therapeutic Impact and Comparative Effectiveness	<p>Section I (Question 27 through 30 and 32) is confidential & proprietary, use subject to IRA 1193(c); FOIA exemptions apply</p> <p>NOTE: Please review the executive summary prior to this section</p>



Question	Sub-Question	Response
Comparative Effectiveness		<p>Biologics have revolutionized the treatment of immune-related diseases by disrupting the inflammatory processes which destroy tissues in the body. They are large, complex molecules that are produced within living cells or microorganisms, through time-consuming, challenging, expensive, and complex processes.</p> <p>There are two classes of biologic treatments: TNF-inhibitors and non-TNF-inhibitors. (Figure 1) TNF-inhibitors have a more potent and wider effect vs. non-TNF-inhibitors (e.g., interleukin (IL) inhibitors such as IL-12/23 and IL-23), which may lead to more infections in patients treated with these agents. [1]</p> <p>TNF-inhibitors are commonly used as first-line biologics given their long history on the market. However, these biologics have the highest level of safety warnings from the FDA (boxed warnings) for serious infections and/or cancer. Safety is a significant concern for Medicare beneficiaries (65+) treated with TNF-inhibitors because they have a high rate of serious infections and mortality vs. untreated Medicare beneficiaries or younger TNF-inhibitor treated patients.</p> <p>Some TNF-inhibitors have high rates of immunogenicity measured by anti-drug antibodies (ADAs), which means the immune system reacts against these biologics or causes them to clear faster from the body, rendering these TNF-inhibitors less effective. TNF-inhibitors also have challenges maintaining long-term durability, requiring additional medications (immunomodulators and corticosteroids) with high levels of costly adverse events (cancer, fractures, diabetes, hypertension, glaucoma, infections and mortality). [Refer to reference 19 in Q30] TNF-inhibitors are typically used in combination with immunomodulators and corticosteroids to improve their effectiveness. This combination can increase the risk of cancer and infections, and these risks increase with age. [2,3]</p> <p>TNF-inhibitors do not fully meet the needs of all patients</p> <ul style="list-style-type: none"> *Significant percentage of patients on TNF-inhibitors do not respond to initial treatment (up to 30%) [4] *Patients aged 60+ on TNF-inhibitors are 70% less likely to respond to treatment vs. younger patients [5] *TNF-inhibitors lose their effect over time (up to 40% of patients), as early as three months, and patients on them may experience severe adverse events [6] *Patients aged 60+ starting TNF-inhibitors have significantly higher discontinuation rates vs. younger patients (25% vs. 7%), most often due to loss of response [5] *TNF-inhibitors have a higher rate of severe adverse events (hospitalizations, surgeries, infections, death and cancer) in patients aged 65+ vs. younger patients [7] <p>For patients who have had an inadequate response to a TNF-inhibitor, it is suggested they switch to another biologic agent with a different mechanism of action (e.g., IL-12/23, IL-23, integrin inhibitor).</p>



Question	Sub-Question	Response
		<p>STELARA® is a significant therapeutic advance over TNF-Inhibitors, developed to address the safety concerns (boxed warnings) associated with TNF-inhibitors and treat patients who do not respond well to TNF-inhibitors. [8]</p> <p>STELARA® is an effective treatment option for chronic, debilitating immune-related diseases, and is indicated for use in moderate-to-severe Crohn’s Disease (CD), moderate-to-severe Ulcerative Colitis (UC), moderate-to-severe Plaque Psoriasis (PsO), and active Psoriatic Arthritis (PsA).</p> <p>STELARA® (the only IL-12/23 inhibitor) delivers:</p> <ul style="list-style-type: none"> *Proven Superiority in PsO/PsA against TNF-Inhibitors *In a clinical trial (ACCEPT), STELARA® was superior to TNF-inhibitor ENBREL® in achieving its primary endpoint of 75% improvement in skin clearance (PASI 75) (74% vs. 57%) [9] *In a clinical trial (ECLIPSA), 74% of PsA patients on STELARA® compared to 42% on TNF-inhibitors achieved clearance from enthesitis at 24 weeks [10] *Established long term safety without boxed warnings *The long-term safety of STELARA® in adults (including aged 60+) has been well-demonstrated in the pooled analysis of clinical trials across all indications up to five years, as well as in registry data. [11–13] (Table 1) *STELARA® has never had boxed warnings, unlike TNF-inhibitors which have boxed warnings for infections and cancer *Compared to STELARA®, TNF-inhibitors were associated with up to almost three-fold higher risk of hospitalization due to serious infections in PsO or PsA [14] *Rapid onset of action *Patients saw symptom improvement in stool frequency and rectal bleeding, as soon as day seven (UC) [15] *Significant effectiveness over TNF-Inhibitors *A psoriasis patient registry (PSOLAR) reported higher discontinuation rates for TNF-inhibitors (up to 44%) vs. STELARA® (8%) among first-line biologic users [16] *Increased persistency - Patients stayed on treatment longer *STELARA® patients were 66% more likely to stay on therapy vs. TNF-inhibitor (HUMIRA®) at two years [17] *Reduced need for corticosteroids and immunomodulators *In UC, STELARA® patients used significantly less corticosteroids (57% lower odds) and immunomodulators (24% lower odds) vs. 6 months prior to initiating STELARA® (Table 2) [18] *Fewer injections per year compared to TNF-inhibitors *STELARA® is dosed every eight weeks in CD/UC, and every 12 weeks in PsO/PsA *For the most prescribed TNF-inhibitors (ENBREL®/HUMIRA®), dosing can be as frequent as weekly or bi-weekly across all indications <p>Therefore, STELARA® is a significant therapeutic advance over TNF-inhibitors, with a more favorable safety profile (no</p>



Question	Sub-Question	Response
		<p>boxed warnings), proven superiority (PsO), and has significantly more patients staying on treatment longer vs. TNF-inhibitors.</p> <p>THERAPEUTIC ALTERNATIVES (Table 3):</p> <p>Therapeutic Alternative in CD/PsO/PsA:</p> <p>IL-12/23 inhibitors and IL-23 inhibitors share the IL-23 mechanism of action and are part of the same chemical class of non-TNF inhibitors and same therapeutic class of biologics. SKYRIZI® is the market-leading IL-23, with the most overlapping indications (CD/PsO/PsA) to STELARA® (the only IL-12/23 inhibitor).</p> <p>Therapeutic Alternative in UC:</p> <p>ENTYVIO® is the therapeutic alternative to STELARA®. ENTYVIO® (a gut-selective integrin receptor antagonist) is the only treatment that meets two of the three CMS properties for determining STELARA®'s therapeutic alternative: chemical class (non-TNF-inhibitor), and therapeutic class (biologic). In addition, STELARA® and ENTYVIO® are the only treatments in the non-TNF-inhibitor class of drugs that are FDA approved for UC (SKYRIZI® has filed for UC with the FDA).</p> <p>CROHN'S DISEASE (THERAPEUTIC ALTERNATIVE – SKYRIZI®):</p> <p>CD affects the gastrointestinal tract from mouth-to-anus causing inflammation, ulcers, pain, and bleeding. Ulcers in the intestine can appear as if a rake was pulled across the lining of the colon. CD complications can include infections, blocked intestines, and drainage near or around the anus due to inflammation, and development of fistulas (tunnels between intestine and bladder, vagina, and skin through which feces can pass).</p> <p>CD patients have high healthcare utilization driven by disease-related hospitalizations (47% of patients) and surgeries (75% of patients). [19][20] Surgery can result in an ostomy (hole connecting the intestine to outside of the body, allowing feces to pass through to a pouch). Ten years from diagnosis, patients with CD have an increased risk (46%) of surgery (most commonly removal of part of the intestines). Among patients requiring surgery, up to 48% may require additional surgery over a 10 year timeframe. [21] Costs per CD-related hospitalizations range from nearly \$30,000 without surgery to approximately \$60,000 with surgery (2019). [22]</p> <p>STELARA® has demonstrated longer-term safety and durable efficacy (up to five years) compared to its therapeutic alternative SKYRIZI® (data up to one year) in addressing these symptoms and providing longer-term clinical remission.</p>



Question	Sub-Question	Response
		<p>In STELARA® clinical trial, IM-UNITI trial (vs. placebo) and long-term extension (Table 4):</p> <ul style="list-style-type: none"> *53% of patients treated with STELARA® were in clinical remission at one year, and among these patients, 59% maintained clinical remission at five years [23] *51% of patients in remission were not taking steroids (steroid-free remission) at five years [24] *Overall adverse event rates were similar to placebo [24] *Patients treated with STELARA® every eight weeks were 40% less likely to be hospitalized or require surgery at two years [25] *Reductions in hospitalizations and surgeries was further substantiated by real-world evidence [RWE] where STELARA® has shown nearly 30% reduction in hospitalizations and surgeries after 12 months of treatment vs. the 12 months prior to treatment [26] <p>In SKYRIZI® FORTIFY trial (vs. Placebo) and pooled phase-III analyses:</p> <ul style="list-style-type: none"> *57% of CD patients achieved clinical remission at one year (per label) *Overall adverse event rates were similar to placebo per label *Invasive blood tests to monitor liver function are required (up to at least 12 weeks) for SKYRIZI® resulting in additional costs to Medicare and increased travel burden on Medicare beneficiaries and caregivers <p>SKYRIZI® does not have published long-term efficacy or safety data beyond one year.</p> <p>STELARA® is recommended in clinical guidelines for CD.</p> <p>American College of Gastroenterology (ACG) and American Gastroenterological Association (AGA)[27,28]</p> <ul style="list-style-type: none"> *Recommend STELARA® for treatment of moderate-to-severe CD in patients who have failed previous therapies including oral agents or TNF-inhibitors, or in patients who have had no previous exposure to TNF-inhibitors <p>ULCERATIVE COLITIS: (THERAPEUTIC ALTERNATIVE – ENTYVIO®):</p> <p>UC is characterized by chronic inflammation and ulcerations in the large intestine (colon and rectum). UC can lead to surgical removal of the colon, and patients are at increased risk of colon cancer. As with CD, surgery can result in an ostomy (hole connecting the intestine to outside of the body, allowing feces to pass through to a pouch). ENTYVIO® only works in the gut and does not help treat other immune-related conditions that may coexist in the skin and joints, while STELARA® does.</p> <p>There are currently no published head-to-head clinical trials in UC between STELARA® and its therapeutic alternative,</p>



Question	Sub-Question	Response
		<p>ENTYVIO®. Comparative data comes from observational studies and indirect comparisons of clinical trials.</p> <p>In the STELARA® UNIFI phase III trial, 45% patients treated with STELARA® achieved UC clinical remission (normal/close to normal number of stools per day, no rectal bleeding, and no or mild disease on colonoscopy) at one year and 58% maintained UC clinical remission at four years. (Table 4) [29,30] In the ENTYVIO® GEMINI phase III trial, 42% of patients who continued to receive ENTYVIO® were in clinical remission at one year. [31]</p> <p>Comparative analyses of STELARA® and ENTYVIO® in UC patients show: *STELARA® has a ~six-times higher likelihood of achieving clinical remission vs. ENTYVIO® in patients who have already tried at least one biologic (indirect analyses of clinical trial data) [32] *Safety of STELARA® and ENTYVIO® was similar in older patients (60+) [33] *STELARA® patients remained on treatment longer vs. ENTYVIO® (66% vs. 50%) at three years [34]</p> <p>STELARA® starts as infusion and transitions to subcutaneous injection, while ENTYVIO® starts as infusion and may transition to subcutaneous injection every 2 weeks.</p> <p>STELARA® offers the convenience of a self-injection every eight weeks following IV starter dose. ENTYVIO® is administered in a healthcare setting as an infusion every eight weeks, or as a subcutaneous injection every 2 weeks after two IV starter doses.</p> <p>STELARA® is recommended in clinical guidelines for UC and suggested over ENTYVIO® in specific patient population</p> <p>American Gastroenterological Association (AGA) [35] *Recommends STELARA® for treatment of moderate-to-severe UC over no treatment *Suggests STELARA®, rather than ENTYVIO®, in patients who did not respond to infliximab (TNF-inhibitor) to induce remission</p> <p>PSORIASIS: (THERAPEUTIC ALTERNATIVE – SKYRIZI®):</p> <p>PsO affects the skin causing pain, itching, burning, and scaling. If $\geq 3\%$ of the body is covered with psoriasis plaques or if there are large areas of plaques on the face, palms, or soles of the feet patients are considered to have moderate to severe psoriasis. About 20% of these patients suffer from anxiety and depression and have a 20% increased risk of cancer (lymphoma, lung, bladder). [36,37]</p>



Question	Sub-Question	Response
		<p>STELARA® and SKYRIZI® have demonstrated long-term safety and durable efficacy (up to 5 years) in addressing PsO symptoms.</p> <p>*In a clinical trial long-term extension study at five years, approximately 70% of STELARA® patients achieved the primary endpoint of PASI 75 (at least 75% improvement in skin clearance)[38]</p> <p>*In a clinical trial comparing STELARA® and SKYRIZI®, both products demonstrated comparable safety. Up to 82% of SKYRIZI® patients achieved PASI 90 (90% improvement in skin clearance) vs. up to 51% of STELARA® patients, at one year [39]</p> <p>STELARA® has FDA approval in pediatric PsO (ages 6 and older) while SKYRIZI® is only approved in adults</p> <p>STELARA® pediatric indications are supported by clinical data from two separate clinical trials</p> <p>*CADMUS: 70% of adolescent STELARA® patients achieved a score of 0 (clear) or 1 (minimal) on their physician’s global assessment (PGA) of skin clearance; scale of 0-5 at week 12 [40]</p> <p>*CADMUS Jr: 77% of STELARA® patients aged 6-11 achieved PGA 0/1 at week 12 [41]</p> <p>STELARA® is recommended in clinical guidelines for PsO</p> <p>Joint American Academy of Dermatology-National Psoriasis Foundation (AAD-NPF) [42,43]:</p> <p>*The AAD-NPF specifically notes that STELARA® is recommended as a monotherapy for difficult to treat areas of psoriasis including nails, scalp, palms, and soles</p> <p>*Recommends STELARA® for the treatment of PsO of any severity when associated with PsA as a monotherapy treatment option for use in adult patients</p> <p>*Recommends STELARA® for the treatment of moderate-to-severe PsO as an effective therapy for adolescents 12 years and older. Pediatric guidelines were written prior to FDA STELARA® approval in patients aged 6-11</p> <p>PSORIATIC ARTHRITIS (THERAPEUTIC ALTERNATIVE – SKYRIZI®):</p> <p>PsA is characterized by any combination of joint inflammation resulting in pain, stiffness, swelling, and reduced range of motion (arthritis), inflammation where tendons or ligaments attach to bone such as at the heel, causing swelling and pain (enthesitis), swelling of an entire finger or toe (dactylitis), and psoriasis of the nails and skin. Compared to patients without PsA, PsA patients have four-fold higher total direct healthcare costs. [44]</p> <p>There are currently no published head-to-head clinical trials in PsA between STELARA® and its therapeutic alternative, SKYRIZI®. Comparative data comes from observational studies and indirect comparisons of clinical trials.</p>



Question	Sub-Question	Response
		<p>STELARA® and SKYRIZI® demonstrate efficacy in the treatment of PsA</p> <p>In a clinical trial, 44% of STELARA® patients achieved ACR20 (20% improvement in key PsA measure) at week 24.[45] In a separate clinical trial, 57% of SKYRIZI® patients achieved ACR20 at week 24. [46] STELARA® efficacy was maintained at one year. [45]</p> <p>In a pooled analysis of clinical trial data, STELARA® has demonstrated that it inhibits joint damage (radiographic progression) in patients with active PsA. In a separate clinical trial SKYRIZI® also had no radiographic progression. [46,47]</p> <p>STELARA® continues to demonstrate longer-term safety vs. SKYRIZI®</p> <p>A pooled safety analysis including phase II and phase III studies of STELARA® in adult patients demonstrated continued safety of STELARA® through up to five years. [48] SKYRIZI® has demonstrated safety for only up to two years.</p> <p>Indirect comparisons of clinical trial data show similar safety and efficacy for STELARA® and SKYRIZI® in PsA.[49]</p> <p>STELARA® has FDA approval in pediatric PsA (ages 6 and older) while SKYRIZI® is only approved for adults.</p> <p>STELARA® is strongly recommended in clinical guidelines for PsA</p> <p>The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) guidelines [50] *Strongly recommend STELARA® for use in patients with active PsA who also have CD or UC</p> <p>CONCLUSION: STELARA® therapeutic alternatives are SKYRIZI® in CD, PsO and PsA and ENTYVIO® in UC. STELARA® represents a significant therapeutic advance over the TNF-inhibitor class due to its superior efficacy in PsO, improved longer-term safety profile including no boxed warnings, low immunogenicity, and fewer injections per year. STELARA® delivers significant value to Medicare beneficiaries by providing a safe, effective option to treat chronic, debilitating, and distressing immune-related diseases. [REDACTED]</p>
	Hyperlink to Citation - Additional Materials for Question 28	[REDACTED]



Question	Sub-Question	Response
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 29: Comparative Effectiveness on Specific Populations	Response to Question 29	<p>Section I (Question 27 through 30 and 32) is confidential & proprietary, use subject to IRA 1193(c); FOIA exemptions apply NOTE: Please review the executive summary prior to this section</p> <p>STELARA® has a broad range of indications to treat chronic, debilitating immune-related diseases (moderate-to-severe Crohn's Disease (CD), moderate-to-severe Ulcerative Colitis (UC), moderate-to-severe Plaque Psoriasis (PsO), and active Psoriatic Arthritis (PsA).</p> <p>STELARA® delivers consistent efficacy and safety, and has a robust and defined clinical profile for many populations across the breadth of indications including specific populations:</p> <ul style="list-style-type: none"> *Elderly patients *Pediatric patients with PsO and PsA *Obese patients *Patients who had inadequate response to prior biologics <p>The therapeutic alternative to STELARA® in CD, PsO and PsA is SKYRIZI®; The therapeutic alternative to STELARA® in UC is ENTYVIO®.</p>



Question	Sub-Question	Response
		<p>ELDERLY PATIENTS:</p> <p>Elderly patients are at higher risk of compromised immune system function, requiring safe and effective biologic treatments. STELARA® demonstrates similar safety and efficacy outcomes in elderly patients as compared to younger patients.</p> <p>The influx of the baby-boomer generation, which began turning 65 and aging into Medicare in 2011, will drive Medicare demographic changes between 2010 and 2030. During that time, the total estimated US population aged 65 or older will increase from 39.7 million to 67.0 million [1], therefore the prevalence of these conditions among Medicare beneficiaries will continue to increase. Aging causes the gradual decline of immune system function, which may make Medicare beneficiaries more susceptible to infections and cancer. [2]</p> <p>Given Medicare beneficiaries are particularly susceptible to serious infections and cancer they need safe and effective medications to treat immune-mediated diseases (e.g., CD/UC/PsO/PsA), like STELARA®, to manage these chronic and debilitating diseases. [3,4]</p> <p>STELARA® has a demonstrated safety profile in elderly patients.</p> <p>Results from a pooled safety analysis of 13 STELARA® clinical studies, including elderly (60+) patients taking STELARA®, showed no difference between the elderly vs. younger patients in the overall rates of side effects and infections across all indications. Importantly, there was also no increased risk of cancer for elderly patients taking STELARA® as compared to other elderly patients in the general population. (Table 1) [5]</p> <p>CD and UC:</p> <p>Approximately 25%–35% of patients with CD/UC are aged >60 [6], and up to 15% of new CD/UC diagnoses occurs among patients >60 years. Furthermore, many CD/UC therapies have been found to increase the risk of infection and malignancy in elderly patients. [3,4,7–9]</p> <p>*A recent gastroenterology publication concluded that based on the safety profile of STELARA®, SKYRIZI® and ENTYVIO®, these treatments should be considered first line treatment options for CD/UC [10]</p> <p>*STELARA® long-term safety profile (including infections and cancer) in older patients (aged 60+) was favorable and consistent with its well-established overall safety profile [11]</p> <p>*SKYRIZI® has no published safety data in CD comparing elderly patients vs. younger patients [10]</p> <p>*ENTYVIO® has shown a consistent safety profile in UC between the elderly vs. younger patients [12,13]</p> <p>PsO and PsA:</p>




Question	Sub-Question	Response
		<p>The prevalence of PsO in the Medicare population ranges from 0.51-1.23%. 15% of patients aged 65+ with PsO have moderate-to-severe disease.[14] Incidence of PsA among patients aged 60+ is approximately 10%. [15] 20% of PsO patients aged 65+ also have PsA. [16]</p> <p>*In a real-world study (PsABio), in patients <60 and ≥60 years of age receiving STELARA® over three years demonstrated similar effectiveness between the two age groups</p> <p>*52% of patients aged <60 and 44% of patients aged 60+ achieved low disease activity after six months of treatment, with effectiveness maintained through three years (Figure 1) [17]</p> <p>*Two real-world studies reported very low incidence of serious infections while utilizing STELARA® for plaque psoriasis in elderly patients (note sample sizes were small) [18,19]</p> <p>*No differences in SKYRIZI® safety or effectiveness were observed between older and younger subjects who received SKYRIZI® [SKYRIZI® PI]</p> <p>PEDIATRIC PATIENTS WITH PsO AND PsA:</p> <p>Limited biologics treatment options exist for PsO and PsA in pediatrics. STELARA® is approved for the treatment of pediatric PsO and PsA (age 6+) while SKYRIZI® is not.</p> <p>The prevalence of PsO among pediatric patients is approximately 1%, of those patients 75% are diagnosed with plaque PsO in the US. [20,21] Pediatric PsA accounts for 6-8% of all cases of pediatric arthritis.[22].</p> <p>*Other than STELARA® (IL-12/23), there are no other IL-23s approved in the pediatric population for PsO or PsA</p> <p>*STELARA® pediatric indication in PsO is supported by clinical data from two separate clinical trials (Table 2, Table 3)</p> <p>*STELARA® pediatric indication for PsA was approved based on the extrapolation of the adult PsA, PsO, and pediatric PsO trials</p> <p>*STELARA® has a convenient dosing schedule of every 12 weeks [STELARA® PI]</p> <p>*Safety and efficacy of SKYRIZI® in pediatric populations is under investigation</p> <p>Pediatric patients are a vulnerable population and need safe and effective treatment options, like STELARA®.</p> <p>OBESE PATIENTS:</p> <p>Obese patients typically have poor responses to certain biologics due to how the drug passes through their body (drug clearance). STELARA® demonstrates consistent efficacy and safety in obese patients.</p> <p>The prevalence of obesity among patients aged 60+ is increasing and is estimated to be ~40%. [23] Obese patients are complex and often have multiple comorbidities (e.g., metabolic diseases, Congestive Heart Failure (CHF)). [24–26]</p>

Question	Sub-Question	Response
		<p>CD:</p> <p>The incidence of CD is rising in parallel with obesity. Contrary to conventional belief, about 15–40% of patients with CD are obese, which might further contribute to the development of CD. [27][28] In addition, obesity typically results in suboptimal responses to treatment. Obese patients on TNF-inhibitors have shown a three-fold risk of having a CD flare compared to non-obese patients. [27]</p> <p>*At week 44 of IM-UNITI, obese patients on STELARA® (55%) had no significant difference in clinical remission vs. normal weight patients (51%) (Figure 2) [29]</p> <p>*SKYRIZI® does not have published efficacy data in obese patients with CD</p> <p>PsA:</p> <p>The prevalence of obesity in patients with PsA is higher than the general population (up to 45% vs. 40%). [25,30] Overweight or obese patients with PsA often have more active disease and a reduced chance of responding to TNF-inhibitors. [26]</p> <p>*In a clinical trial (PSUMMIT-1), STELARA® patients in weight groups >220lbs (100kg) and ≤220lbs (100kg) who responded to treatment, measured by ACR20 and PASI 75 (measures of clinical response), had similar responses, which were maintained over time (week 100) [31]</p> <p>*SKYRIZI® efficacy data in obese PsA patients has not been published</p> <p>Most available treatments for conditions like CD/PsA have lower response rates in obese patients due to the rapid clearing of the drug from their bodies. [27] STELARA® has specific FDA-approved dosing for patients weighing over 220lbs (100kg). Studies have shown no significant difference in treatment response in obese patients with CD or PsA who are on the increased dose (90 mg every 12 weeks). [STELARA® PI] Obese patients with CD/PsA are difficult to treat and are costly to Medicare. STELARA® delivers significant value to obese Medicare beneficiaries.</p> <p>PATIENTS WHO TRIED PRIOR BIOLOGICS UNSUCCESSFULLY:</p> <p>Switching or discontinuing biologics can result in higher health care utilization and increased medical costs vs. remaining on the same biologic. Medicare beneficiaries need safe and effective options, like STELARA®, for those who have tried other biologics unsuccessfully.</p> <p>Up to 30% of CD/UC patients do not respond to their initial TNF-inhibitor treatment. Among those who do respond, about 40% relapse during treatment, some as early as within 3 months. [32][33] Medicare beneficiaries may cycle through several biologics for their treatment of these debilitating diseases, and many have already been on multiple therapies prior to accessing Medicare.</p>



Question	Sub-Question	Response
		<p>CD:</p> <ul style="list-style-type: none"> *40% of STELARA® patients are able to achieve clinical remission at one year among those who previously tried other biologics unsuccessfully [34] *80% of STELARA® patients remained on treatment at one year vs. 65% treated with the TNF-inhibitor HUMIRA®, among patients who were treated with prior biologics [35] *48% of SKYRIZI® patients achieved clinical remission at one year among those who previously tried other biologics unsuccessfully [36] <p>UC:</p> <ul style="list-style-type: none"> *61% of STELARA® patients achieved clinical remission as early as eight weeks, and 79% by one year among those who previously tried other biologics unsuccessfully [37] *79% of patients treated with STELARA® remained on treatment at one year [37] *36.1% of ENTYVIO® patients achieved clinical remission at one year among those who previously tried other biologics unsuccessfully [38] <p>PsO/PsA:</p> <ul style="list-style-type: none"> *63% of STELARA® PsO patients achieved 75% improvement in skin clearance (PASI 75) among those who previously tried other biologics unsuccessfully [39] *39% of STELARA® PsA patients achieved 20% improvement in key PsA measures (ACR20) at one year, among those who previously tried other biologics unsuccessfully [40] *59% of SKYRIZI® PsA patients achieved 20% improvement in key PsA measures (ACR20) at one year, among those who previously tried other biologics unsuccessfully [41] <p>STELARA® has demonstrated effectiveness and safety among patients who have tried prior biologics unsuccessfully, meeting an important unmet medical need.</p>
	Hyperlink to Citation - Additional Materials for Question 29	<div data-bbox="625 1274 1774 1318" style="background-color: black; height: 27px; width: 547px;"></div>



Question	Sub-Question	Response
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	<p>Section I (Question 27 through 30 and 32) is confidential & proprietary, use subject to IRA 1193(c); FOIA exemptions apply NOTE: Please review the executive summary prior to this section</p> <p>STELARA® addresses several unmet needs across approved indications (moderate-to-severe Crohn’s Disease (CD), moderate-to-severe Ulcerative Colitis (UC), moderate-to-severe Plaque Psoriasis (PsO), and active Psoriatic Arthritis (PsA)). These unmet needs include:</p> <ul style="list-style-type: none"> *Lack of treatments with long-term safety, and durability *Reduced concomitant use of corticosteroids and immunomodulators *Reduced patient/caregiver burden <p>CD: CD affects the gastrointestinal tract from mouth to anus causing inflammation, ulcers, pain, and bleeding. Ulcers in the intestine can appear as if a rake was pulled across the lining of the colon. (Figure 1) [1] CD complications can include infections, blocked intestines, drainage near or around the anus due to inflammation, and development of fistulas (tunnels between intestine and other organs (bladder, vagina, skin) through which feces can pass). CD carries a significant financial burden in the US, as high as \$23 billion annually (CPI-adjusted) in direct and indirect costs. [2] By 10 years from diagnosis, patients with CD have an increased risk (46%) of surgery (most commonly removal of part of the intestines). [3] Medicare beneficiaries hospitalized for CD had 70% higher in-hospital mortality compared to commercially insured CD patients. [4]</p>



Question	Sub-Question	Response
		<p>UC: UC consists of chronic inflammation and ulcerations in the large intestine (colon and rectum). (Figure 2) UC can lead to surgical removal of the colon, and patients are at increased risk of colon cancer.[5] UC carries a significant financial burden in the US, as high as \$21 billion annually (CPI-adjusted) in direct and indirect costs. [2] Medicare beneficiaries hospitalized for UC had 86% higher in-hospital mortality compared to commercially insured patients. [6]</p> <p>PsO: PsO affects the skin causing pain, itching, burning, inflammation and scaling. There is a significant stigma towards patients with PsO, due to the visual nature of disease. (Figure 3) Approximately 20% of PsO patients suffer from anxiety and depression, and also have an increased risk of cancer (lymphoma, lung cancer, bladder cancer). [6,7] Patients with PsO also have high comorbidity burden (diabetes, high blood pressure, obesity) relative to the general population. [8]</p> <p>PsA: PsA affects the joints causing pain, stiffness, swelling, inhibits the ability to perform daily tasks, and can lead to disability. In severe cases, joints can become permanently damaged or deformed. (Figure 4) Compared to patients without PsA, PsA patients have four-fold higher total direct healthcare cost. [9]</p> <p>LONG-TERM SAFETY, DURABILITY, AND EFFICACY:</p> <p>There are two classes of biologics treatments: TNF-inhibitors and non-TNF-inhibitors. (Q28 Figure 1) TNF-inhibitors have a more potent and wider effect vs. non-TNF-inhibitors (e.g., interleukin (IL) inhibitors), which may lead to more infections in patients treated with these agents. [10] In fact, TNF-inhibitors have boxed warnings for serious infections and cancers.</p> <p>Since these inflammatory diseases are chronic and lifelong there is continued need for treatment options demonstrating more favorable long-term safety, durability, and effectiveness. Unmet needs that still exist for these indications include a lack of well-established long-term safety, durability, and efficacy among the newly approved non-TNF-inhibitor biologics.</p> <p>*STELARA® has proven consistent long-term safety (no boxed warnings), durable efficacy across all adult indications for up to five years</p> <p>*The long-term safety of STELARA® in adults (including aged 60+) has been well-demonstrated in pooled analyses of STELARA® clinical trials across all indications up to five years. (Table 1) [11][12]</p> <p>USE OF CORTICOSTEROIDS AND IMMUNOMODULATORS:</p>

Question	Sub-Question	Response
		<p>There is a need for medications that reduce use of corticosteroids and immunomodulators, which are often used with TNF-inhibitors to improve effectiveness. [13,14]</p> <p>Medicare beneficiaries (65+) treated with TNF-inhibitors have a higher rate of serious infections and mortality vs. younger patients, or Medicare beneficiaries who were not on these treatments. [15] TNF-inhibitors have challenges maintaining long-term durability, therefore immunomodulators and corticosteroids may be used in combination with TNF-inhibitors to improve effectiveness. (Figures 5,6,7) [14][13]</p> <p>*Patients aged 60+ are already at four-fold higher risk of discontinuing TNF-inhibitors vs. younger patients, most often due to infections [16]</p> <p>*Immunomodulators, particularly when used in combination with TNF-inhibitors also increase the risk of cancer and infections, and such risk increases with age [17,18]</p> <p>*Chronic corticosteroid use can cause significant, costly adverse effects (fractures, diabetes, hypertension, glaucoma, infections and mortality) [19] [20]</p> <p>After one year, STELARA® patients were significantly less likely to use immunomodulators (24%) and corticosteroids (57%) vs. six months prior. (Table 2) [13] STELARA® has demonstrated consistent safety across patients aged 60+ and younger patients for up to five years. [14] [13] SKYRIZI® and ENTYVIO® have also shown reductions in corticosteroid use. [21,22] Patients aged 60+ with high comorbidity burden receiving STELARA® or ENTYVIO® had a lower risk of infection-related hospitalizations vs. those receiving TNF-inhibitors. [23]</p> <p>PATIENT/CAREGIVER:</p> <p>Medications that require ongoing routine monitoring or IV infusion put an additional burden on Medicare beneficiaries and their caregivers, due to travel and procedure time. SKYRIZI® requires invasive blood tests to monitor liver function (up to at least 12 weeks) in CD.</p> <p>ENTYVIO® is administered either as IV infusion every eight weeks for maintenance therapy in a health care setting, or as a subcutaneous injection every two weeks after two IV starter doses. Visits to healthcare settings can lead to additional costs to Medicare, and increased costs and travel burden on beneficiaries and caregivers.</p> <p>STELARA® does not require any routine blood tests or other routine monitoring. In addition, STELARA® offers the convenience of a self-injection every eight weeks following its IV starter dose in CD/UC, and every 12 weeks following subcutaneous starter doses in PsO and PsA.</p>



Question	Sub-Question	Response
		STELARA® offers long-term safety, durability, and efficacy, decreases the use of corticosteroids and immunomodulators, providing a less burdensome treatment option for Medicare beneficiaries and their caregivers.
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	<p>STELARA® delivers significant clinical value to Medicare beneficiaries providing a safe and effective option to treat chronic, debilitating, and distressing immune-related diseases.</p> <p>What Matters to Medicare Beneficiaries: STELARA® treats moderate-to-severe Crohn’s Disease (CD), moderate-to-severe Ulcerative Colitis (UC), moderate-to-severe Plaque Psoriasis (PsO), and active Psoriatic Arthritis (PsA).</p>

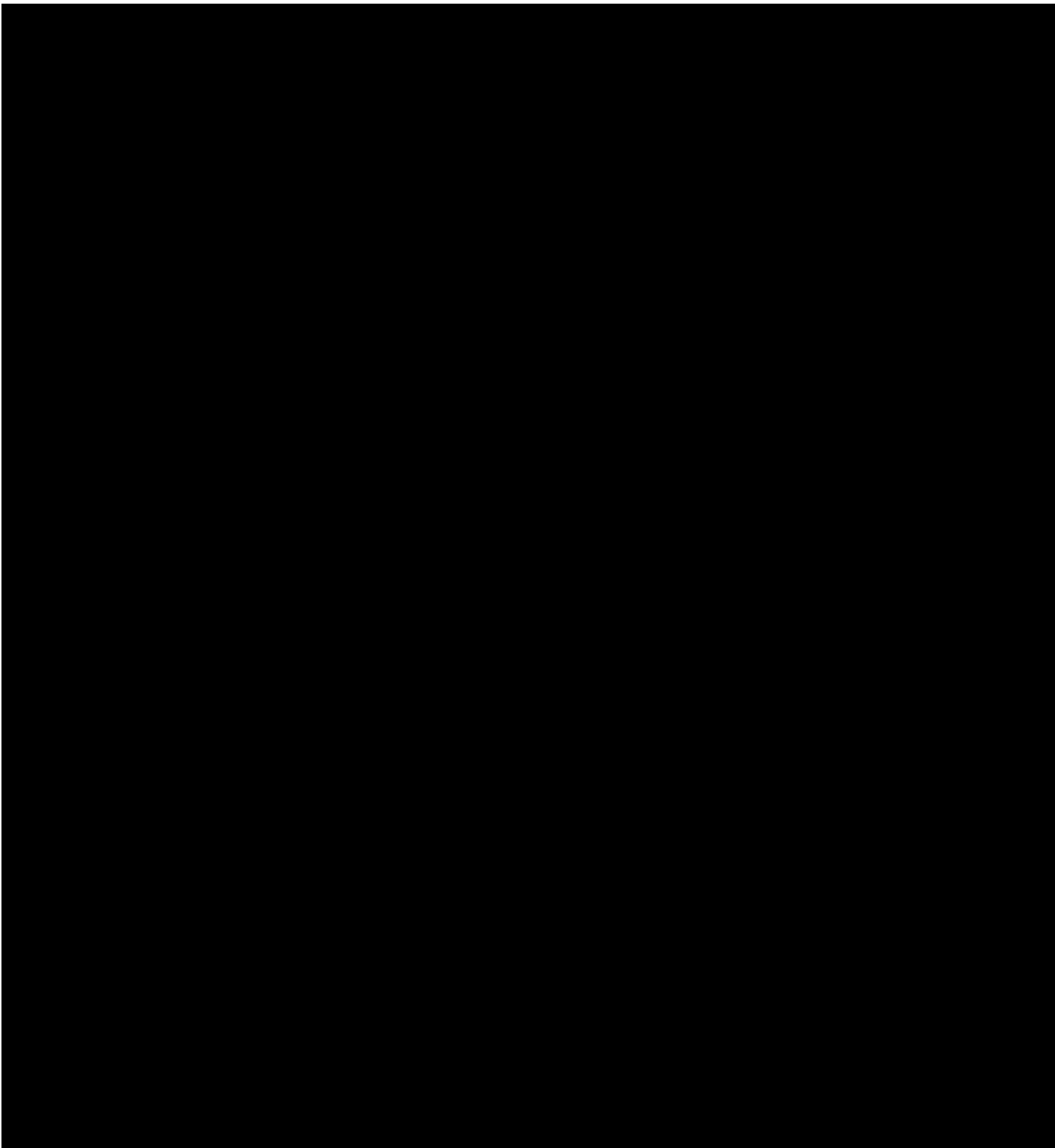


Question	Sub-Question	Response
		<p>STELARA® is the first significant therapeutic advancement over TNF-inhibitors due to its improved safety profile, better tolerability, significant improvement in persistency in all indications, and significantly better efficacy in PsO (vs. ENBREL®, TNF-inhibitor).</p> <p>*Longer-term Efficacy, Demonstrated Safety Profile: The therapeutic alternative for patients living with CD/PsO/PsA to STELARA® is SKYRIZI®. STELARA® has longer-term efficacy and safety data relative to SKYRIZI® in CD. STELARA® is approved for PsO/PsA patients 6+ which demonstrates its safety profile and broader utility in special populations, unlike SKYRIZI® (approved for 18+)</p> <p>*Significant Improvement in Efficacy and Longer-Term Adherence: The therapeutic alternative for patients living with UC to STELARA® is ENTYVIO®. In patients treated with STELARA® (>=1 prior biologics) patients treated have a ~six-fold higher likelihood of achieving clinical remission and stay on therapy for longer than ENTYVIO®</p> <p>BACKGROUND ON DISEASES TREATED BY STELARA®:</p> <p>*Crohn's Disease/Ulcerative Colitis: CD affects the gastrointestinal tract from mouth-to-anus causing inflammation, ulcers, pain, bleeding, and complications including infections, blocked intestines, drainage near or around the anus due to inflammation, and development of fistulas (tunnels between intestine, bladder, vagina, and skin through which feces can pass). UC can cause ulcers in the inner lining of the colon/rectum and complications including surgical removal of the colon resulting in waste being expelled through a hole in the abdomen into a pouch.</p> <p>*Symptoms of CD/UC include severe abdominal pain, frequent, bloody diarrhea, and perforation of the colon, leading to hospitalization and surgery and increased risk of colon cancer.</p> <p>*CD/UC patients have high healthcare utilization driven by hospitalizations (CD-47%, UC-60%) and surgeries (CD-75%, UC-45%). CD/UC-related lifetime healthcare costs are \$377B. Medicare beneficiaries (>=65) requiring CD/UC-related hospitalizations have higher morbidity and mortality vs. younger patients (<65). In-hospital Medicare death rates for patients with CD/UC are almost double the rates vs. younger patients.</p> <p>*Plaque Psoriasis/Psoriatic Arthritis: PsO affects the skin causing pain, itching, burning, inflammation and scaling. There is a significant stigma towards patients with PsO, due to the visual nature of disease. About 20% of PsO patients suffer from anxiety, depression and a 20% increased risk of cancer. PsA affects joints causing pain, stiffness, and swelling. In severe cases, joints become permanently damaged or deformed. PsA patients have four-fold higher total direct healthcare cost vs. patients without PsA.</p> <p>TREATMENT OPTIONS FOR MEDICARE BENEFICIARIES LIVING WITH CD/UC/PsO/PsA:</p>

Question	Sub-Question	Response
		<p>Two classes of biologics (defined by FDA’s formulary drug classification):</p> <ul style="list-style-type: none"> *TNF-inhibitors *Non-TNF-inhibitors <p>Non-biologic treatments:</p> <ul style="list-style-type: none"> *Corticosteroids *Immunomodulators *Topicals and other orals <p>STELARA® IS A SIGNIFICANT THERAPEUTIC ADVANCE OVER TNF-INHIBITORS:</p> <p>TNF-inhibitors are commonly used as first-line biologics given their long history on the market. However, these biologics have the highest level of safety warnings from the FDA (boxed warnings) for serious infections and/or cancer. Medicare beneficiaries (65+) treated with TNF-inhibitors have a high rate of serious infections and mortality vs. younger patients.</p> <p>Challenges with TNF-inhibitors include maintaining long-term durability increasing the need for immunomodulators and corticosteroids to improve effectiveness.</p> <ul style="list-style-type: none"> *Patients aged 60+ have four-fold higher risk of discontinuing TNF-inhibitors vs. younger patients, most often due to infections *Immunomodulators, particularly when used in combination with TNF-inhibitors, increase the risk of cancer and infections, especially with increasing age *Chronic corticosteroid use causes significant, costly adverse effects (fractures, diabetes, infections, mortality) <p>Additionally, STELARA® has low immunogenicity rates, no routine tuberculosis monitoring requirements, and fewer injections per year vs. TNF-inhibitors.</p> <p>In CD, STELARA® patients stayed on treatment longer, used less corticosteroids and immunomodulators, and had fewer infections than HUMIRA® (TNF-inhibitor). In adults with PsO, STELARA® (70%) has better efficacy than ENBREL® (57%) in its ability to reduce skin plaques (75% improvement from baseline).</p> <p>FOR CD/PsO/PsA, THE THERAPEUTIC ALTERNATIVE TO STELARA® IS SKYRIZI®:</p> <p>STELARA® (only IL-12/23) and SKYRIZI® (IL-23) are part of the same chemical class of non-TNF inhibitors, same therapeutic class of biologics and IL-12/23 and IL-23 inhibitors share the IL-23 mechanism-of-action. SKYRIZI® is the</p>

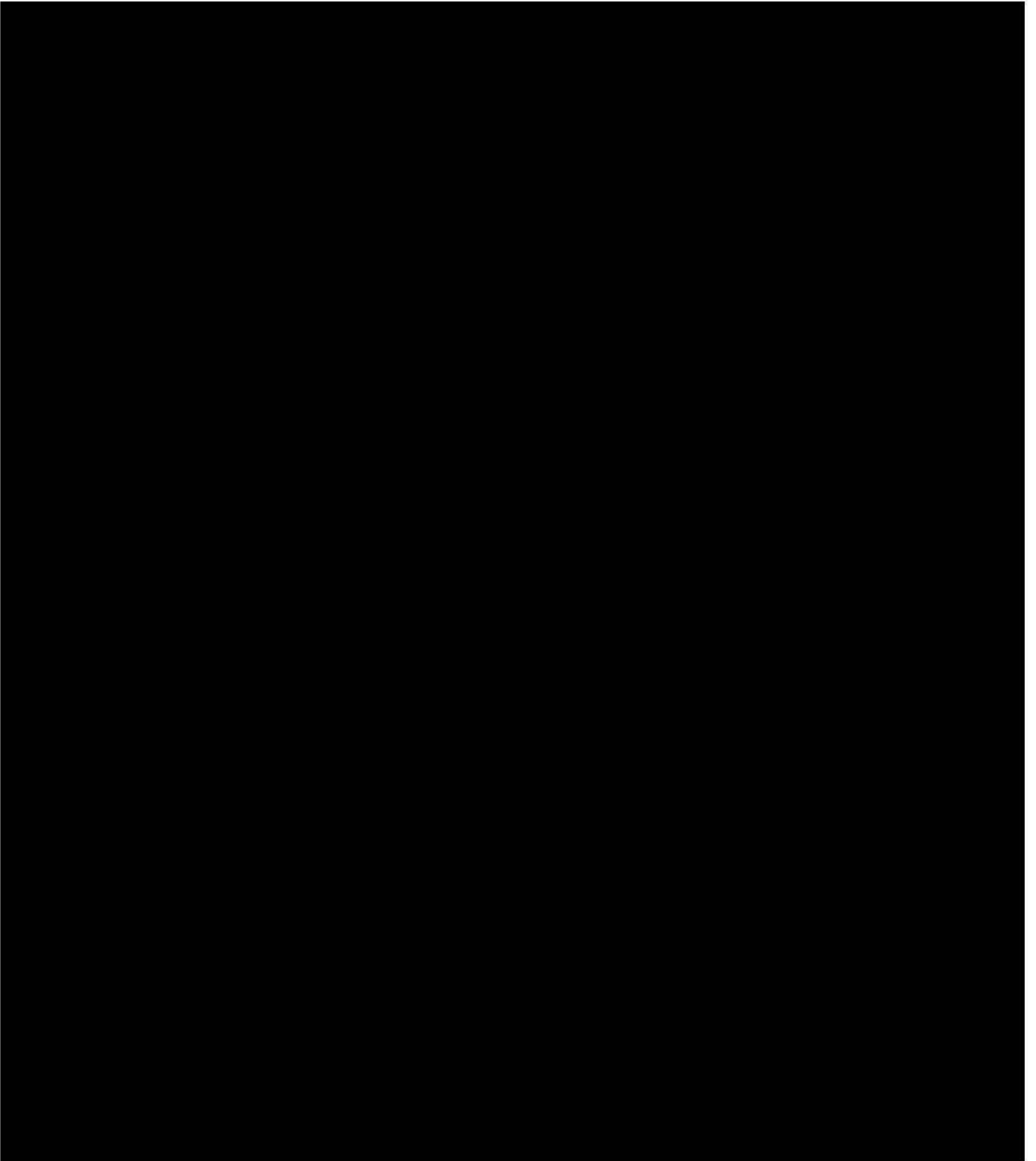


Question	Sub-Question	Response
		<p>market-leading IL-23, with the most overlapping indications (CD/PsO/PsA) to STELARA® (IL-12/23).</p> <p>STELARA® has longer-term efficacy and safety data relative to SKYRIZI® in CD.</p> <ul style="list-style-type: none"> *STELARA® has a safety profile that is consistent across pivotal trials, with long-term extensions up to five years *STELARA® is approved for children aged 6+ for PsO/PsA, further demonstrating its safety profile and broader utility in specific populations, unlike SKYRIZI® (approved for 18+) *STELARA® and SKYRIZI® show similar clinical remission (resolved symptoms) rates (~52%) at one year, and indirect comparisons show no statistically significant differences in CD *STELARA®, unlike SKYRIZI®, has real-world data demonstrating ~30% reductions in CD-related hospitalizations and surgeries after 12 months *STELARA®, unlike SKYRIZI®, does not require monitoring for liver toxicity in CD *In PsA patients who also have CD/UC, guidelines list STELARA® as a strong recommendation for PsA treatment, while SKYRIZI® is only conditionally recommended <p>FOR UC, THE THERAPEUTIC ALTERNATIVE TO STELARA® IS ENTYVIO®:</p> <p>ENTYVIO® (a gut-selective integrin receptor antagonist) is the only treatment that meets 2 of 3 CMS properties for a therapeutic alternative to STELARA®: chemical class (non-TNF-inhibitor), and therapeutic class (biologic). In addition, STELARA® and ENTYVIO® are the only treatments in the non-TNF-inhibitor class of drugs that are FDA approved for UC (SKYRIZI® has filed for UC with FDA).</p> <ul style="list-style-type: none"> *STELARA® has ~six-fold higher odds of achieving clinical remission vs. ENTYVIO® in UC patients who have already tried ≥1 biologic, with a similar safety profile *Patients stayed on treatment longer with STELARA® (66%) vs. ENTYVIO® (50%) at three years *STELARA®, unlike ENTYVIO®, treats other immune-mediated conditions outside of the gut that coexist in the skin and joints (occurs in up to 40% of patients) <p>CONCLUSION:</p> <p>Based on the demonstrated significant clinical value of STELARA® [REDACTED]</p>



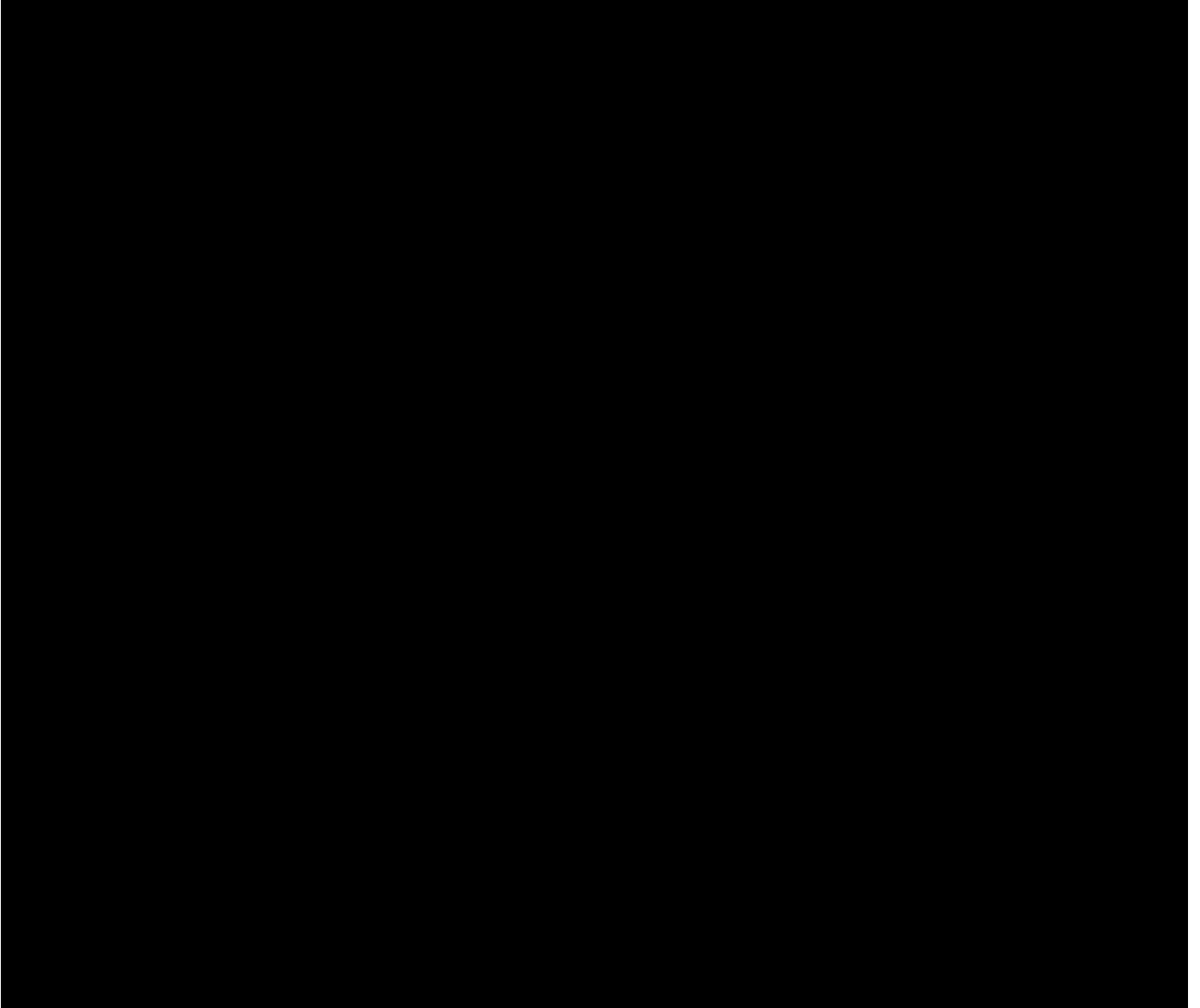
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Table 3. Comparison of attributes of alternative therapies

STELARA® Therapeutic Alternative Analysis

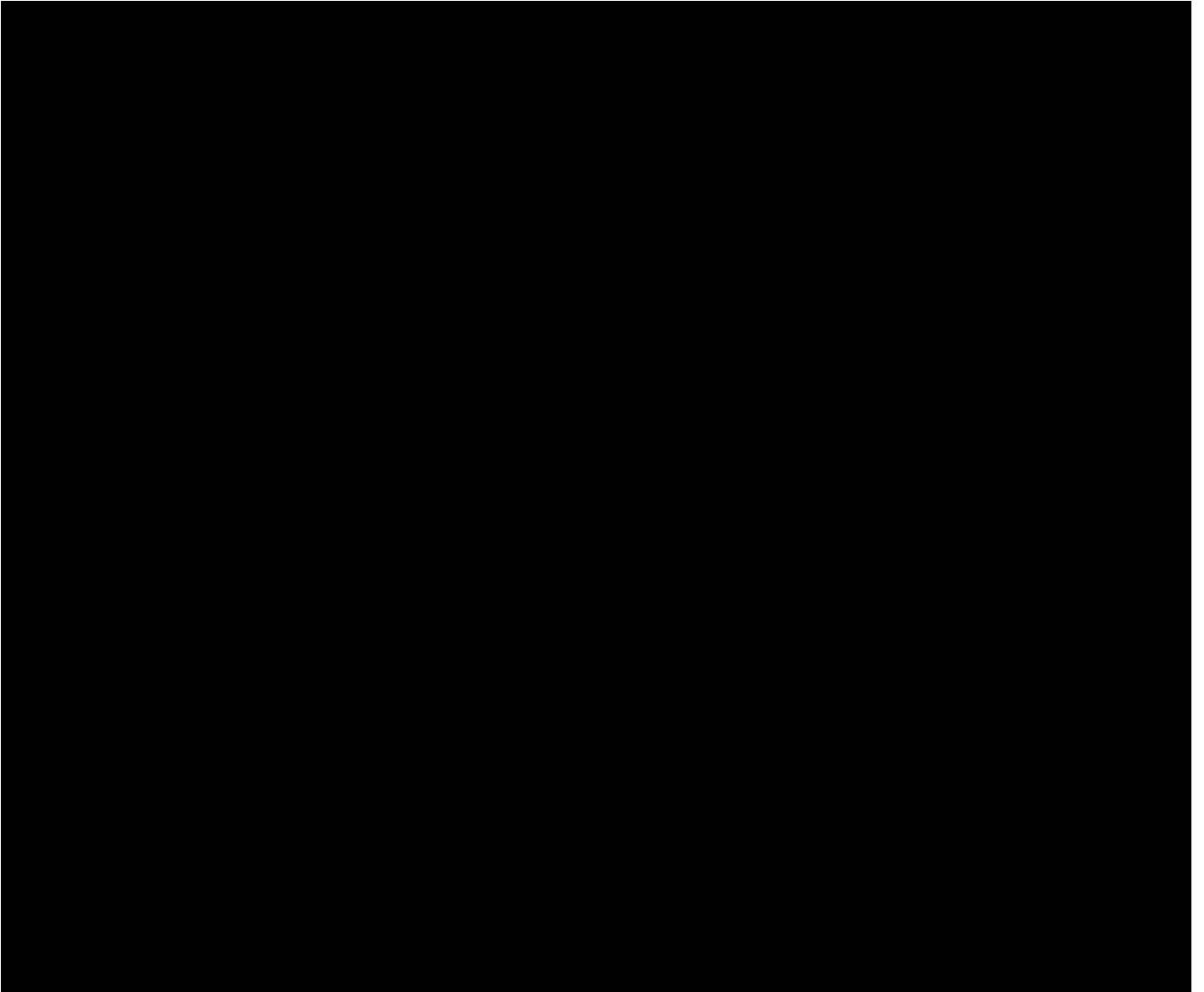
		Therapeutic Alternatives				
Brand Name	STELARA®	SKYRIZI® CD, PsO, PsA	ENTYVIO® UC	HUMIRA®	ENBREL®	REMICADE®
Therapeutic Class	Non-TNF Inhibitor	✓	✓	X	X	X
MOA	IL-12/23 inhibitor	X IL-12	✓ IL-23	X	X	X
Chemical Class	Biologic	✓	✓	✓	✓	✓

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Table 4. Remission Data From Pivotal Trials in CD and UC: IM-UNITI Long-term Extension (LTE) and UNIFI LTE

Remission Data at 1 Year and 5 Years in Crohn's Disease (CD)			
	STELARA®	Placebo	P-value
Clinical remission ^a at 1 year ¹	53%	36%	$P=0.005$
Clinical remission at 5 years among patients who achieved clinical remission at 1 year ³	59%	N/A	
Remission Data at 1 Year and 4 Years in Ulcerative Colitis (UC)			
	STELARA®	Placebo	
Clinical remission ^b at 1 year ²	45%	26%	$P=0.001$
Symptomatic remission ^c at 4 years among patients who achieved clinical remission at 1 year ³	69%	N/A	
<p>Abbreviations: CD, Crohn's disease; N/A: not applicable; UC, ulcerative colitis</p> <p>^aClinical remission in CD was defined as a composite measure of the signs and symptoms of Crohn's disease activity. This was based on the Crohn's Disease Activity Index (CDAI) with a score of <150</p> <p>^bClinical remission in UC was defined as normal or close to normal number of stools per day, no rectal bleeding, and no or mild disease on colonoscopy.</p> <p>^cSymptomatic remission in UC was defined as normal or close to normal number of stools per day and no rectal bleeding</p>			

1. Feagan BG, Sandborn WJ, Gasink C, Jacobstein D, Lang Y, Friedman JR, Blank MA, Johannis J, Gao LL, Miao Y, Adedokun OJ, Sands BE, Hanauer SB, Vermeire S, Targan S, Ghosh S, de Villiers WJ, Colombel JF, Tulassay Z, Seidler U, Salzberg BA, Desreumaux P, Lee SD, Loftus EV Jr, Dieleman LA, Katz S, Rutgeerts P; UNITI–IM-UNITI Study Group. Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease. *N Engl J Med*. 2016 Nov 17;375(20):1946-1960.
2. USPI. STELARA (ustekinumab) [Internet]. Janssen Biotech, Inc.; Available from: <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf>.
3. Janssen Scientific Affairs, LLC. Data on File.

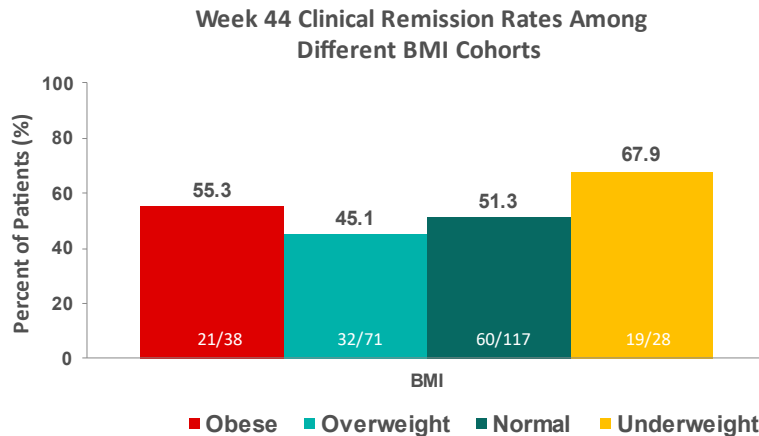


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Figure 2. Clinical Remission stratified by BMI

Clinical Remission in STELARA-treated Patients Stratified by BMI



Separate analyses of the every 8 week STELARA and every 12 week STELARA arms also showed no significant differences in Clinical Remission rates among the four subgroups.

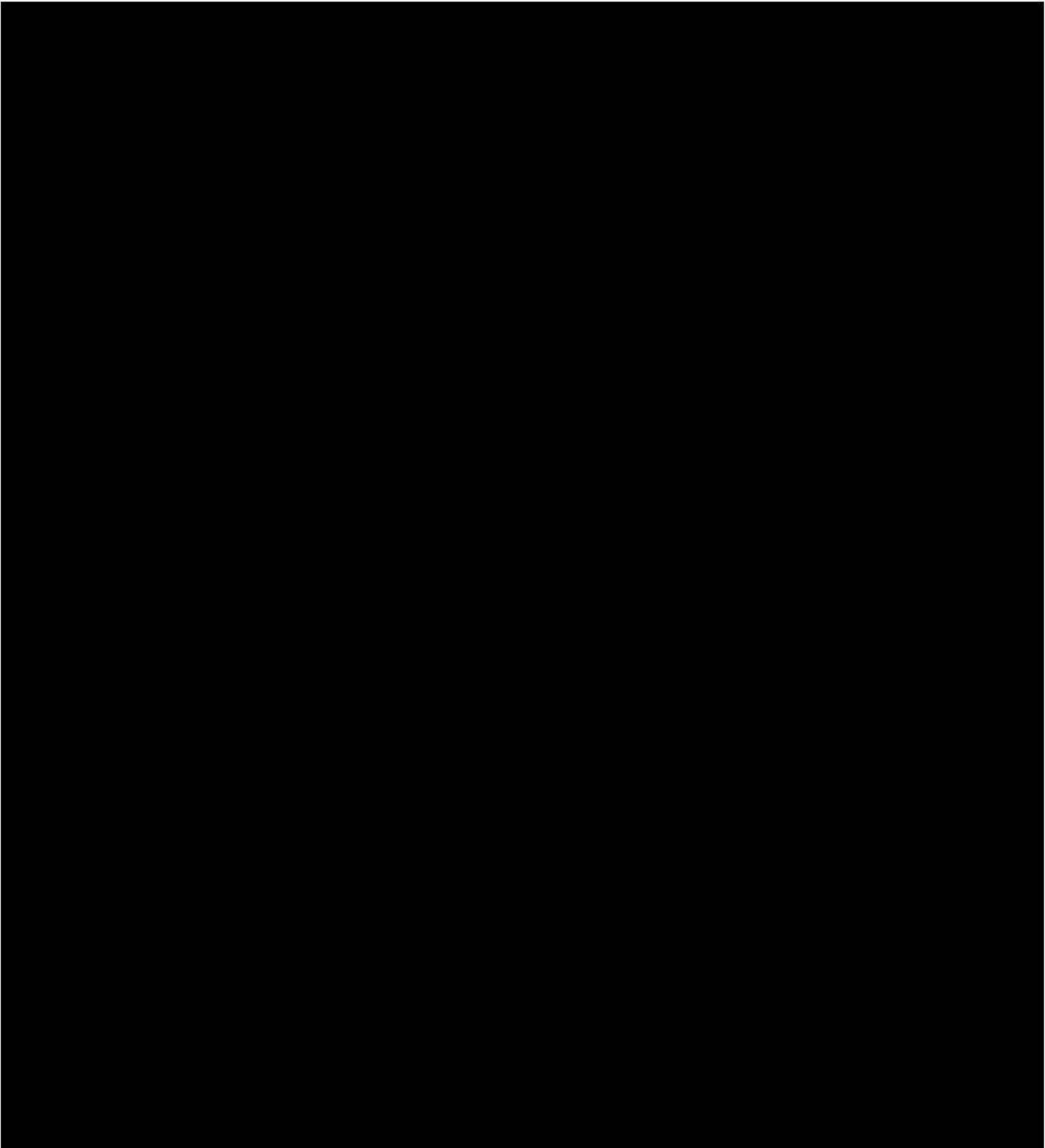
There were also no significant differences seen in Clinical Remission rates when comparing patients with prior biologic exposure and those who were biologic naive.

28 (11.0%) were underweight, 117 (46.1%) had normal BMI, 71 (28.0%) were overweight, and 38 (15.0%) were obese.
p=0.89, underweight BMI vs. other BMIs.

Adapted from Wong et al. *Inflamm Bowel Dis* 2020;Epub 19Aug;izaa214doi:10.1093/ibd/izaa214

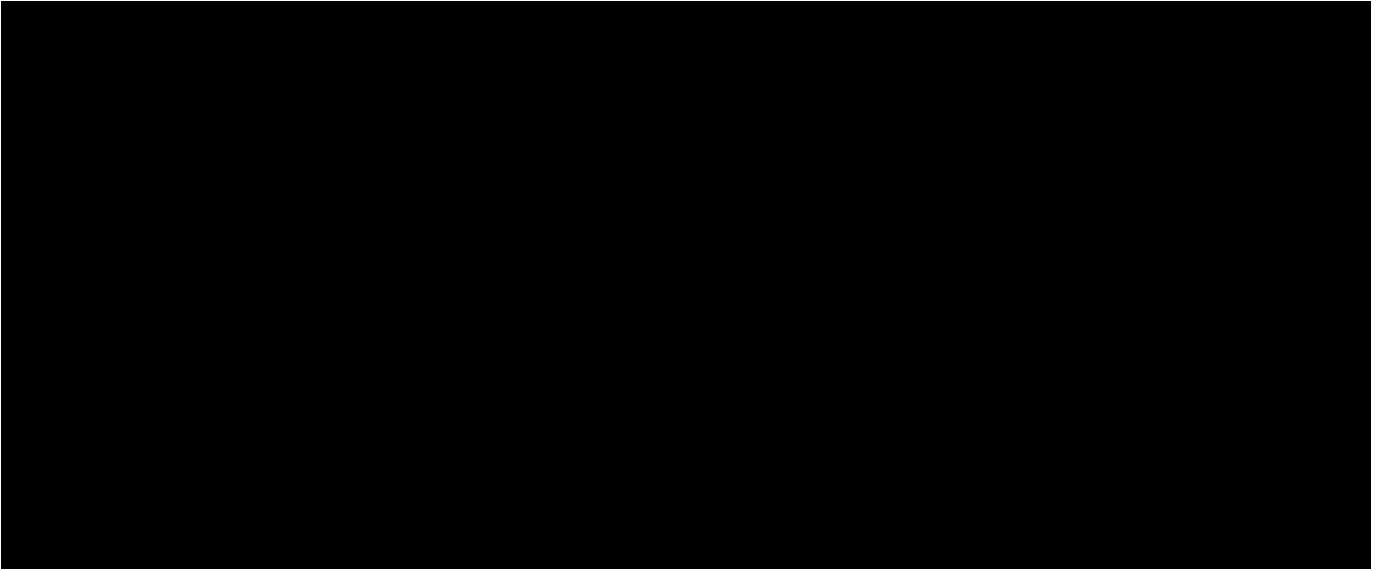
Adapted from Wong ECL, Marshall JK, Reinisch W, et al. Body Mass Index Does Not Impact Clinical Efficacy of Ustekinumab in Crohn's Disease: A Post Hoc Analysis of the IM-UNITI Trial. *Inflamm Bowel Dis*. 2020;27:848–854. ***If printing, please print in color to best understand the graph.***

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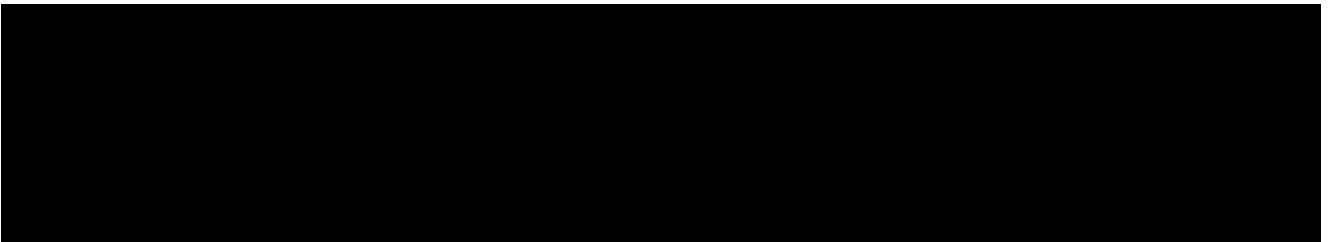
Table 3. STELARA® efficacy in pediatric patients

Table. Efficacy Results at week 12

	STELARA (n=44)
Week 12	
PGA 0/1 ^a	77.3 (62.2, 88.5)
PGA 0 ^c	38.6 (24.4, 54.5)
PASI 75 ^b	84.1 (69.9, 93.4)
PASI 90 ^b	63.6 (47.8, 77.6)
PASI 100 ^c	34.1 (20.5, 49.9)
Mean CDLQI change from baseline (±SD) ^b	-6.3 ± 6.43
CDLQI 0/1 ^{cd} , n (%)	24/39 (61.5%)
Data presented as % (95% CI) unless otherwise noted	
Abbreviations: PGA, physician's global assessment; PASI 75/90/100, ≥75%/≥90%/100% improvement in psoriasis area and severity index; CDLQI, Children's Dermatology Life Quality Index	
^a Primary endpoint	
^b Major secondary endpoints	
^c Other secondary endpoints	
^d Among patients with CDLQI >1 at baseline	

Adapted from Philipp S, Menter A, Nikkels A, et al. Ustekinumab for the treatment of moderate-to-severe plaque psoriasis in pediatric patients (≥6 to <12 years of age): efficacy, safety, pharmacokinetic, and biomarker results from the open-label CADMUS Jr study. [published online ahead of print March 16, 2020]. Br J Dermatol. 2020;183:664–672.

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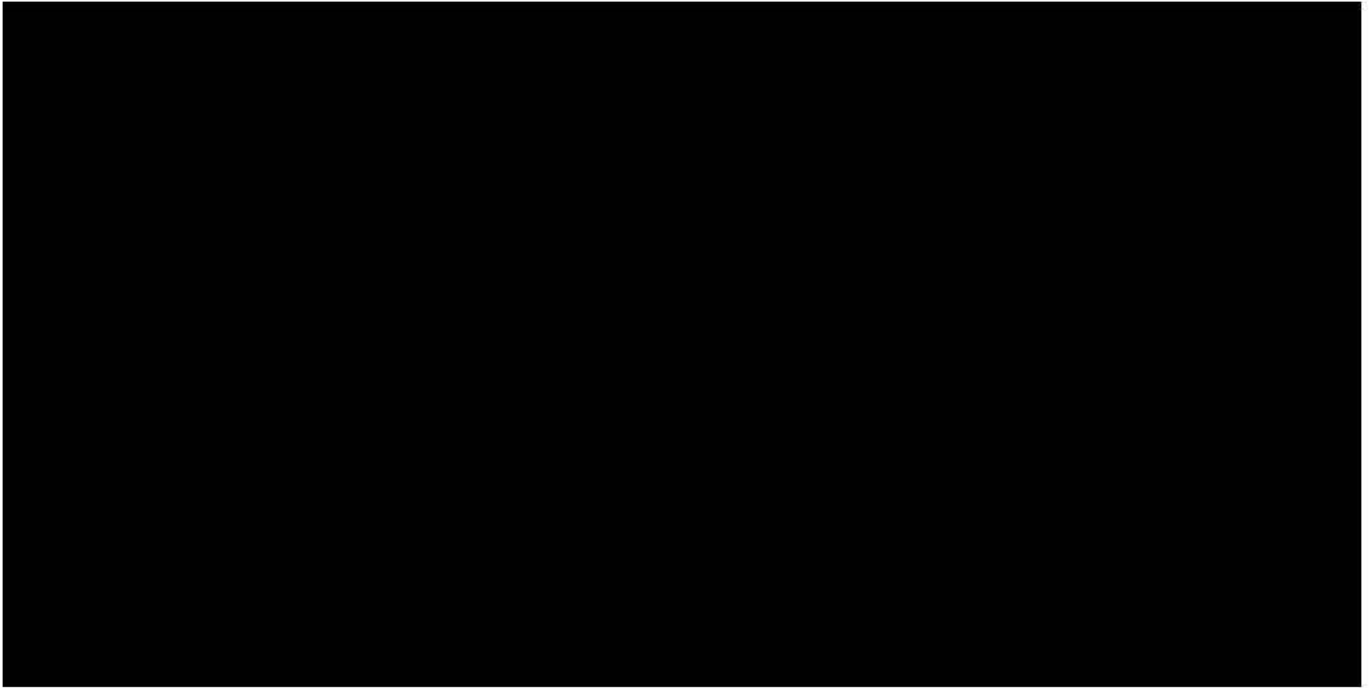
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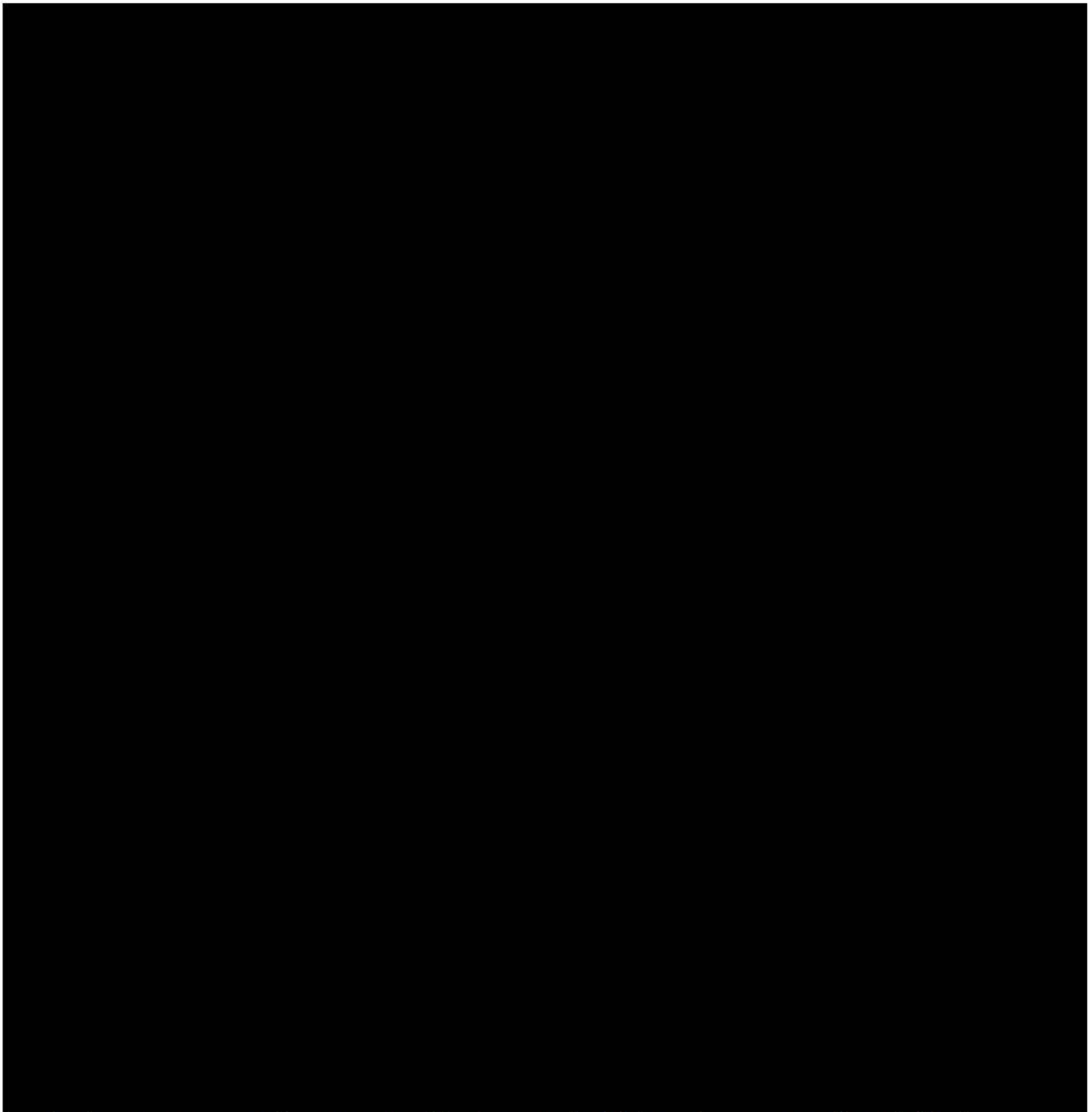
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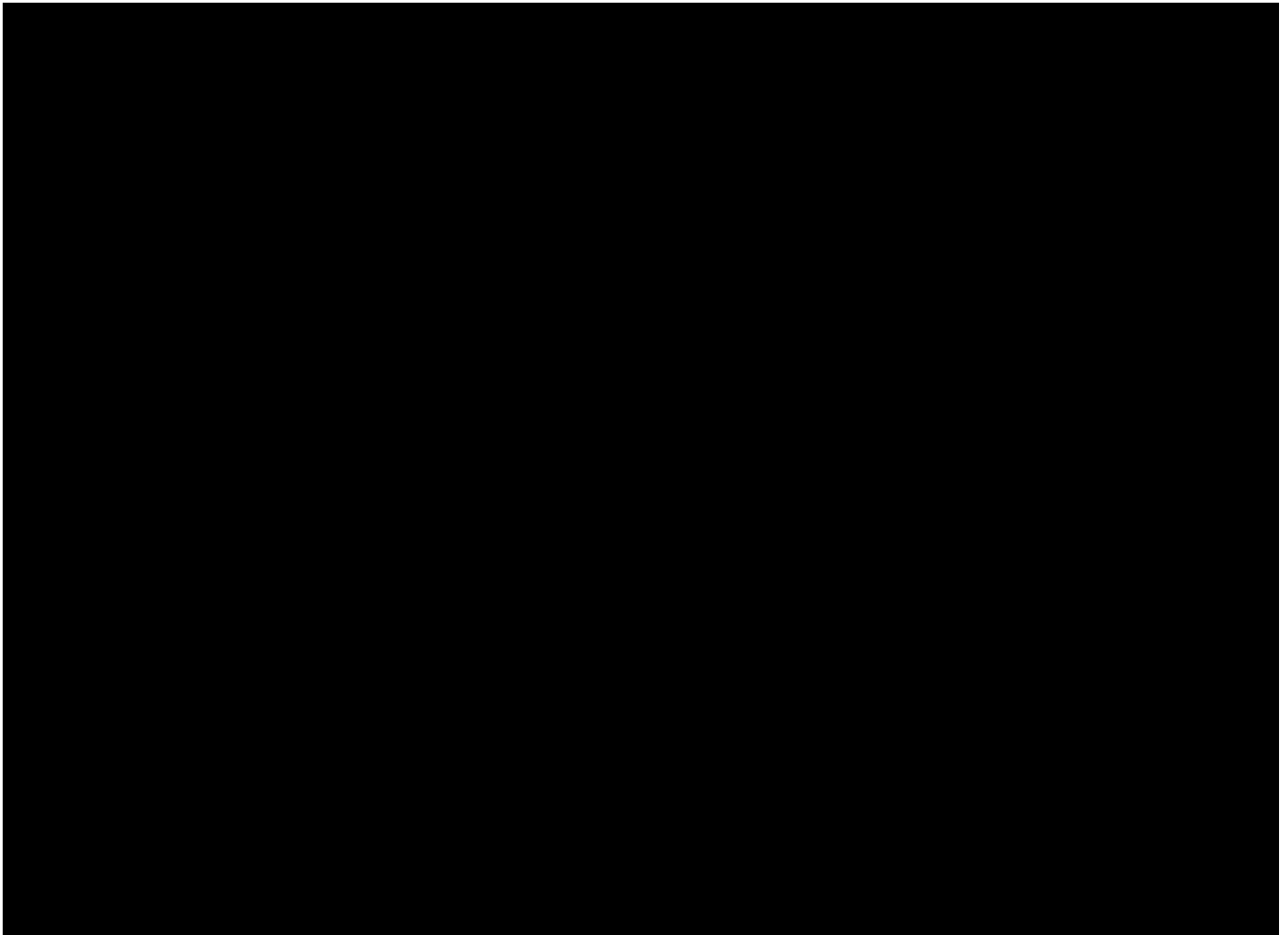
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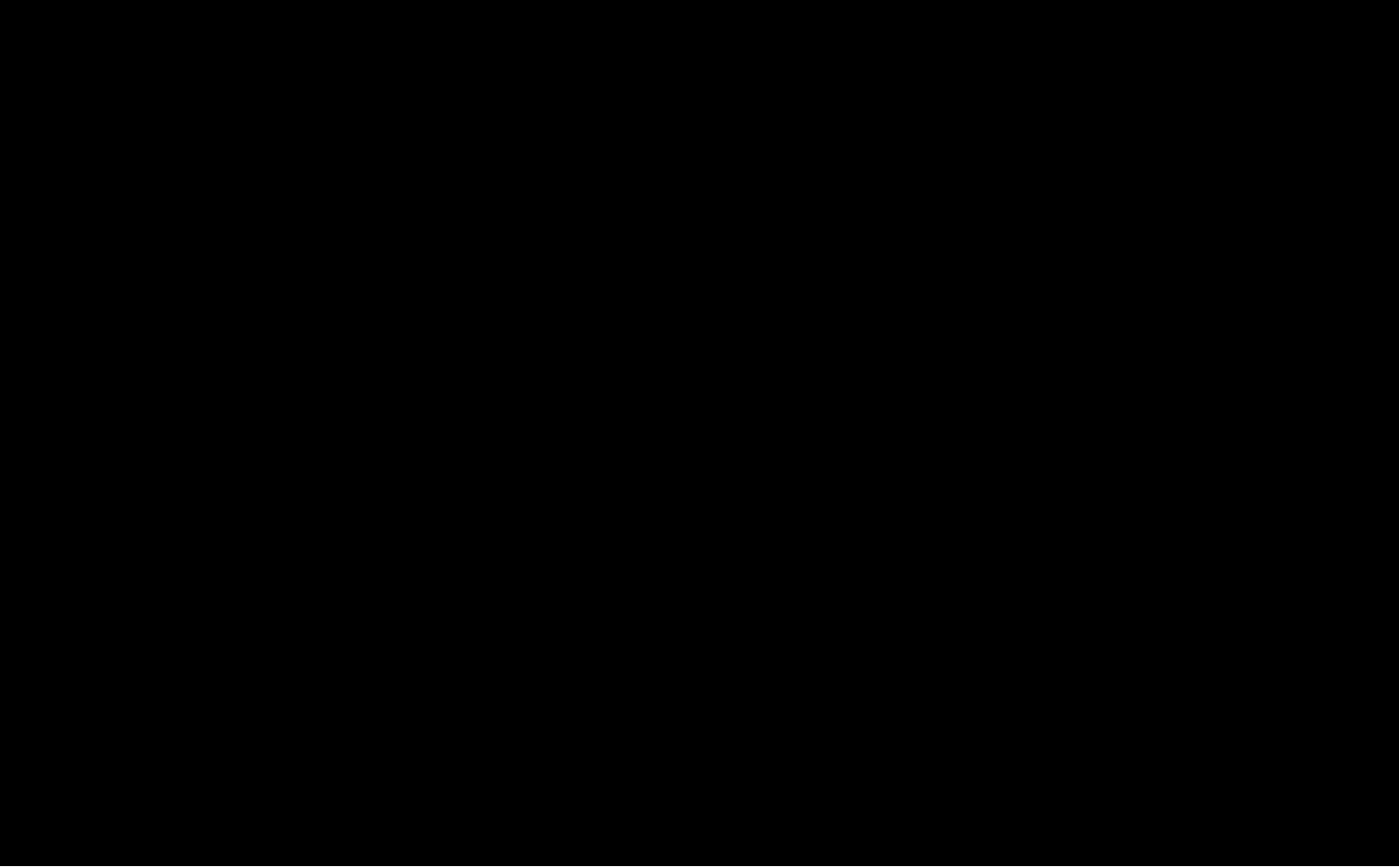
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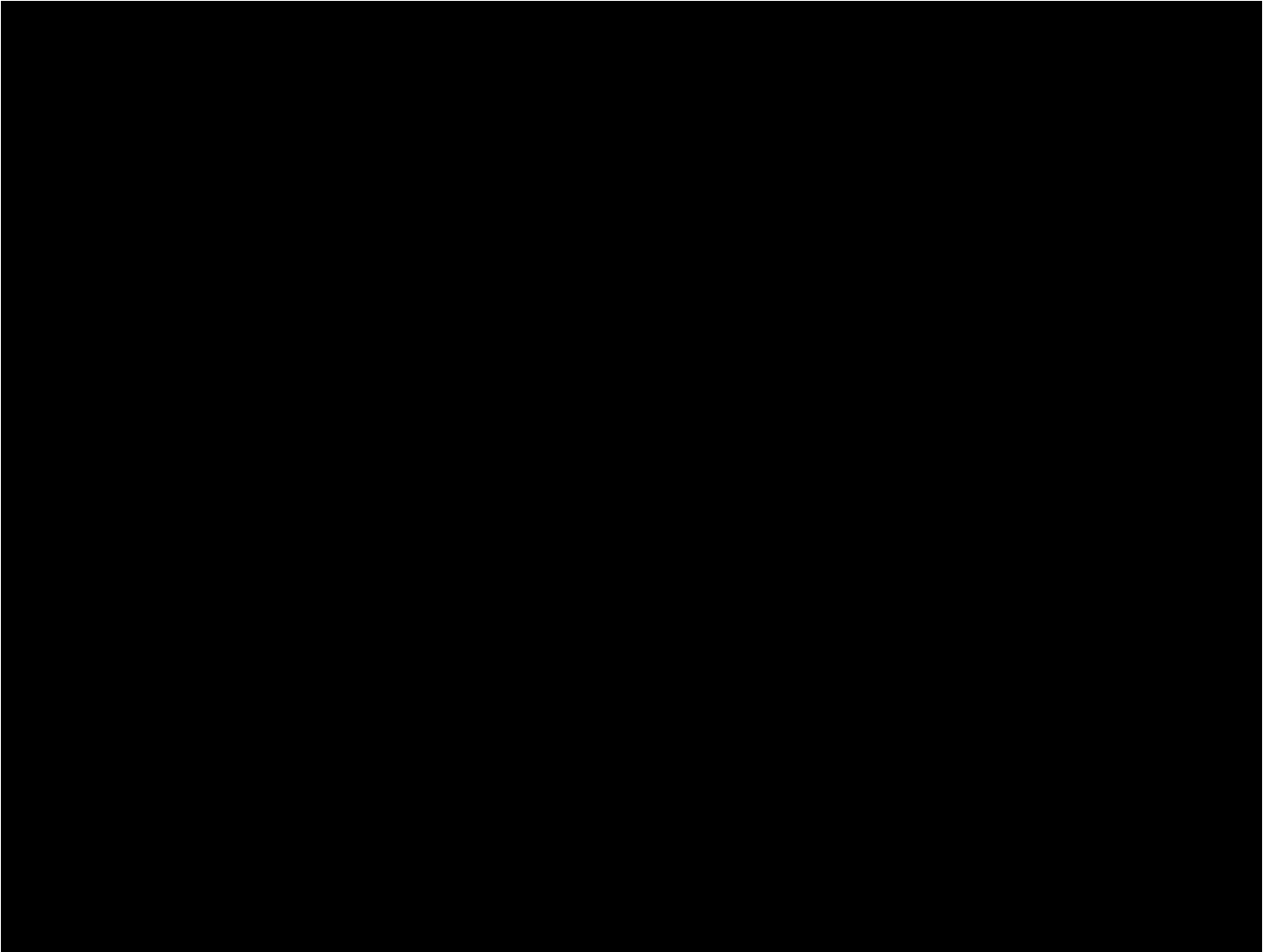
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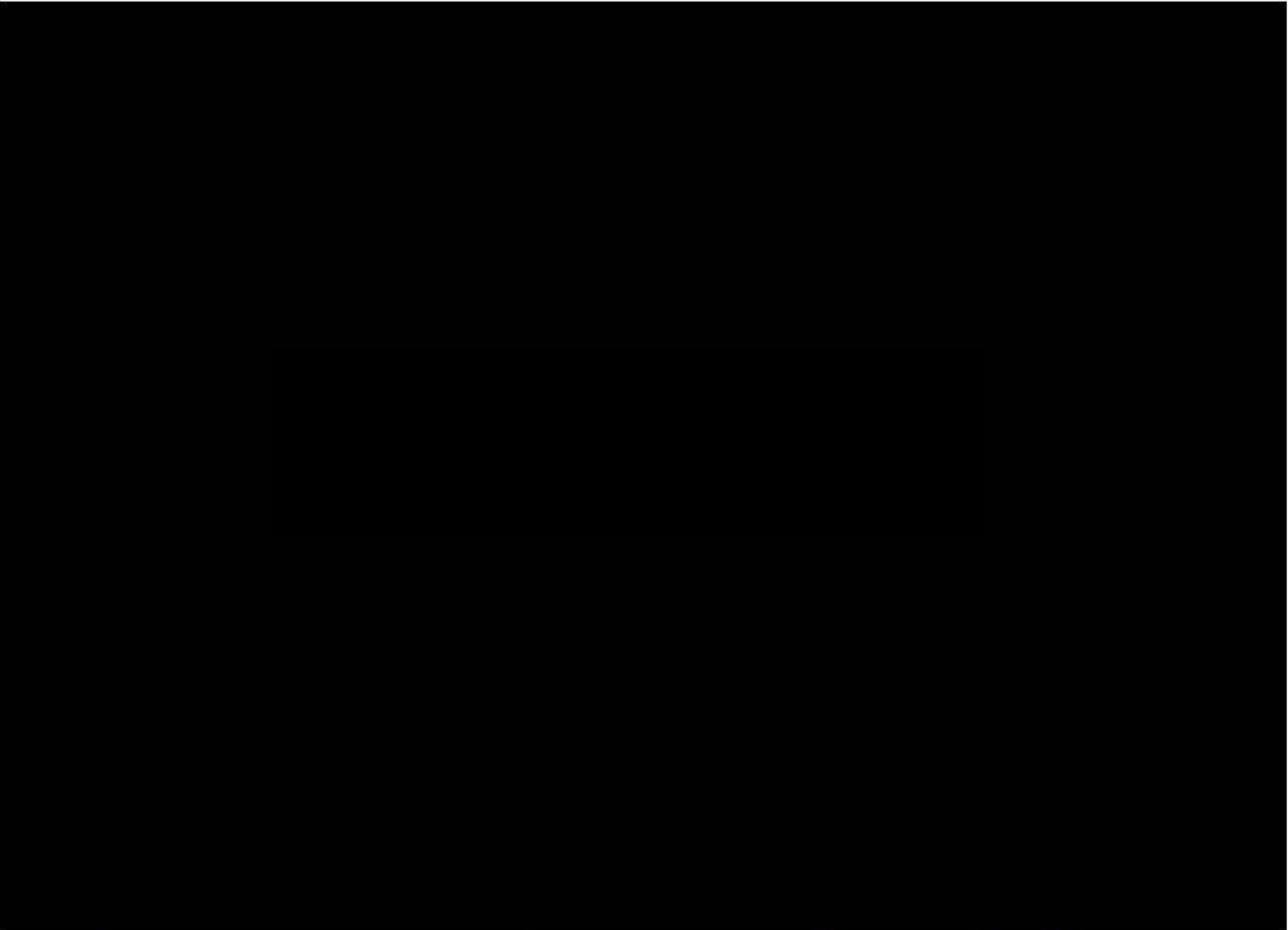
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Table 2. Non-biologic treatment use in UC patients 6 months post- vs pre- STELARA® initiation

	Pre- STELARA® n (%)	Post- STELARA® n (%)	Odds ratio¹ post vs pre (95% CI), p-value
	N = 4,147		
Immunomodulators	605 (14.6)	474 (11.4)	0.76 (0.70, 0.82), <0.001*
5-ASA	1,655 (39.9)	1,154 (27.8)	0.58 (0.55, 0.62), <0.001*
Corticosteroids	2,565 (61.9)	1,712 (41.3)	0.43 (0.41, 0.46), <0.001*
Continuous use of ≥ 60 days ²	1,097 (26.5)	728 (17.6)	0.59 (0.54, 0.65), <0.001*
Continuous use of ≥ 90 days ²	576 (13.9)	439 (10.6)	0.73 (0.66, 0.82), <0.001*
Cumulative use of ≥ 60 days ²	1,346 (32.5)	851 (20.5)	0.54 (0.50, 0.58), <0.001*
Cumulative use of ≥ 90 days ²	775 (18.7)	558 (13.5)	0.68 (0.62, 0.74), <0.001*
Opioids	729 (17.6)	628 (15.1)	0.84 (0.76, 0.92), <0.001*
Antidiarrheals	194 (4.7)	148 (3.6)	0.75 (0.65, 0.88), <0.001*
GI antispasmodics	441 (10.6)	300 (7.2)	0.66 (0.58, 0.74), <0.001*

Notes:

1. Obtained from a logistic regression model estimated by generalized estimating equation adjusting for repeated measures per patient.
2. For continuous use of corticosteroids, a gap of 14 days of supply was tolerated (ie, the episode of use continued even when there were no days of supply of corticosteroids for 14 consecutive days). For cumulative use of corticosteroids, nonoverlapping days of supply were summed.

*P-value ≤ 0.05

Abbreviations: 5-ASA, 5-aminosalicylic acid; CI, confidence interval; GI, gastrointestinal; OR, odds ratio.

Adapted from Zhdanova M, Zhao R, Manceur AM, Kachroo S, Lefebvre P, Pilon D. Persistence and Dose Escalation During Maintenance Phase and Use of Nonbiologic Medications Among Patients With Ulcerative Colitis Initiated on Ustekinumab in the United States. *Crohn's Colitis* 360. 2023 Sep 4;5(3):otad045.

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Question 30

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	AARP
	Respondent Email	
	Who is completing this form?	PAT
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
	Response to Question 29	

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	

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Question	Sub-Question	Response
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Question 31: Patient and Caregiver Experience	Response to Question 31	<p>Response</p> <p>AARP, which advocates for the more than 100 million Americans age 50 and over, is pleased to submit the following comments in response to the Centers for Medicare and Medicaid Services' (CMS) Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions. AARP commends CMS for soliciting feedback from the public and appreciates its efforts to ensure that patients, caregivers, and health care providers have a voice in the negotiation process. ..Data shows that brand-name drug prices have increased dramatically faster than inflation for decades. List prices for the 25 brand-name drugs with the highest total Medicare Part D spending in 2021 have increased by an average of 226 - or more than tripled - since they first entered the market. Data also shows that all but one of the top 25 drugs' lifetime price increases greatly exceeded the corresponding annual rate of general inflation (Consumer Price Index All Urban Consumers for All Items; CPI-U) over the period that each product has been on the market (i.e., product launch date until May 2023). For example, the price of Enbrel (Etanercept), used to treat rheumatoid arthritis and psoriatic arthritis, has increased by 701% since coming to market in 1998, and the price of Januvia (Sitagliptin), used to treat diabetes, has increased by 275% since entering the market in 2006. Further, the median price of a new brand-name prescription drug is now approximately \$200,000 per year, so even relatively small percentage price increases can translate into thousands of dollars and put life-saving medications out of reach of the patients who need them...High prescription drug prices can negatively affect older adults' health and financial security. [REDACTED], a Medicare enrollee from [REDACTED], is living with a health condition and takes Imbruvica to treat the condition. "The Imbruvica is doing what it's supposed to do. My CLL is in remission. But it's a drug that you take forever unless you can't tolerate it for one reason or another." [REDACTED]'s annual out-of-pocket costs for Imbruvica have increased year after year, paying \$8,500 in 2016 to \$11,768 in 2020. "The Imbruvica in 2020 was 13% of our gross income. ... If you have one prescription [that] costs you 13% of your GROSS income, that's obscene. My husband's question to me when we were paying these outrageous amounts was, 'What do you do if you can't afford it? You just die.' It shouldn't go up every year after it's been approved and there's no more research and development." ..AARP fiercely believes that the needs of Medicare beneficiaries should remain paramount as the agency implements the Negotiation Program. In 2022, about 1 in 5 adults ages 65 and up either skipped, delayed, took less medication than was prescribed, or took someone else's medication last year because of concerns about cost. It is not fair or right to ask patients and taxpayers to continue paying for high prescription drug prices that are the result of broken markets. ..Successful implementation of the new federal law will help reduce prescription drug prices and costs and ensure that millions of older Americans are better able to access the prescription drugs they need at a price they can afford. The Medicare drug price negotiation process will also finally allow CMS to push back on indiscriminately escalating drug prices and ensure that taxpayer funds are paying for value – all while saving billions for Medicare and its beneficiaries. The CBO estimates that the Negotiation Program will save Medicare and the American taxpayers nearly \$98.5 billion over 10 years, reduce the budget deficit by \$25 billion in 2031, and save Medicare Part D enrollees \$7 billion in 2031 due to lower out-of-pocket costs and premiums. ..This is about real people whose lives are on the line. For decades, older Americans have paid the highest prices in the world for prescription drugs - often three</p>
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Question	Sub-Question
Question 32: Executive Summary	Response to Question 32

Response
times higher than people in other countries. Now is the time to change that. Effective implementation of this Program will represent a major victory for older Americans and their families across the country who are struggling to afford their prescriptions. It will also help encourage and appropriately reward the development of truly innovative products. AARP stands ready to assist in any way with these and other efforts to bring down drug prices and help older Americans afford the medications and treatments they need. If you have any questions, please do not hesitate to contact me or Gidget Benitez at gbenitez@aarp.org...Sincerely, ..Nancy LeaMond.Executive Vice President and Chief Advocacy & Engagement Officer



October 2, 2023

Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Dear Dr. Seshamani:

AARP, which advocates for the more than 100 million Americans age 50 and over, is pleased to submit the following comments in response to the Centers for Medicare and Medicaid Services' (CMS) Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions. AARP commends CMS for soliciting feedback from the public and appreciates its efforts to ensure that patients, caregivers, and health care providers have a voice in the negotiation process.

Data shows that brand-name drug prices have increased dramatically faster than inflation for decades. List prices for the 25 brand-name drugs with the highest total Medicare Part D spending in 2021 have increased by an average of 226%—or more than tripled—since they first entered the market.¹ Data also shows that all but one of the top 25 drugs' lifetime price increases greatly exceeded the corresponding annual rate of general inflation (Consumer Price Index All Urban Consumers for All Items; CPI-U) over the period that each product has been on the market (i.e., product launch date until May 2023).² For example, the price of Enbrel (Etanercept), used to treat rheumatoid arthritis and psoriatic arthritis, has increased by 701% since coming to market in 1998, and the price of Januvia (Sitagliptin), used to treat diabetes, has increased by 275% since entering the market in 2006.³ Further, the median price of a new brand-name prescription drug is now approximately \$200,000 per year,⁴ so even relatively small percentage price increases can translate into thousands of dollars and put life-saving medications out of reach of the patients who need them.

High prescription drug prices can negatively affect older adults' health and financial security. [REDACTED], a Medicare enrollee from [REDACTED], is living with a health condition and takes Imbruvica to treat the condition. "The Imbruvica is doing what it's supposed to do. My CLL is in remission. But it's a drug that you take forever unless you can't tolerate it for one reason or another." [REDACTED]'s annual out-of-pocket costs for Imbruvica have increased year after year, paying \$8,500 in 2016 to \$11,768 in 2020. "The Imbruvica in 2020 was 13% of our gross income. ... If you have one prescription [that] costs you 13% of your GROSS income, that's

¹ Leigh Purvis, "Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market." Washington, DC: AARP Public Policy Institute, August 10, 2023. <https://doi.org/10.26419/ppi.00202.001>.

² *Id.*

³ *Id.*

⁴ Benjamin N. Rome, Alexander C. Egilman, and Aaron S. Kesselheim, "Trends in Prescription Drug Launch Prices, 2008–2021," *Journal of the American Medical Association* 327, no. 21 (2022): 2145–47, <https://jamanetwork.com/journals/jama/fullarticle/2792986>; Deena Beasley, "U.S. New Drug Price Exceeds \$200,000 Median in 2022," *Reuters*, January 5, 2023, <https://www.reuters.com/business/healthcare-pharmaceuticals/us-new-drug-price-exceeds-200000-median-2022-2023-01-05/>.

obscene. My husband's question to me when we were paying these outrageous amounts was, 'What do you do if you can't afford it? You just die.' It shouldn't go up every year after it's been approved and there's no more research and development."

AARP fiercely believes that the needs of Medicare beneficiaries should remain paramount as the agency implements the Negotiation Program. In 2022, about 1 in 5 adults ages 65 and up either skipped, delayed, took less medication than was prescribed, or took someone else's medication last year because of concerns about cost.⁵ It is not fair or right to ask patients and taxpayers to continue paying for high prescription drug prices that are the result of broken markets.

Successful implementation of the new federal law will help reduce prescription drug prices and costs and ensure that millions of older Americans are better able to access the prescription drugs they need at a price they can afford. The Medicare drug price negotiation process will also finally allow CMS to push back on indiscriminately escalating drug prices and ensure that taxpayer funds are paying for value – all while saving billions for Medicare and its beneficiaries. The CBO estimates that the Negotiation Program will save Medicare and the American taxpayers nearly \$98.5 billion over 10 years,⁶ reduce the budget deficit by \$25 billion in 2031,⁷ and save Medicare Part D enrollees \$7 billion in 2031 due to lower out-of-pocket costs and premiums.⁸

This is about real people whose lives are on the line. For decades, older Americans have paid the highest prices in the world for prescription drugs - often three times higher than people in other countries. Now is the time to change that. Effective implementation of this Program will represent a major victory for older Americans and their families across the country who are struggling to afford their prescriptions. It will also help encourage and appropriately reward the development of truly innovative products. AARP stands ready to assist in any way with these and other efforts to bring down drug prices and help older Americans afford the medications and treatments they need. If you have any questions, please do not hesitate to contact me or Gidget Benitez at gbenitez@aarp.org.

Sincerely,



Nancy A. LeaMond
Executive Vice President and
Chief Advocacy & Engagement Officer

⁵ Stacie B. Dusetzina et al., "Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022," *JAMA Network Open* 6, no. 5 (2023): e2314211, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012>.

⁶ Congressional Budget Office, "Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14," https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf. Accessed September 27, 2023.

⁷ Congressional Budget Office, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act," <https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf>. Accessed September 27, 2023.

⁸ *Id.*

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	AiArthritis (International Foundation for Autoimmune & Autoinflammatory Arthritis)
	Respondent Email	
Question 27: Prescribing Information	Who is completing this form?	PAO Ustekinumab is approved for the following AiArthritis disease indications: Psoriatic Arthritis (PsA) (adults and children over the age of 6) and Crohn's Disease. The Mechanism of Action (MoA) is human interleukin-12 and 23 antagonist (IL-12/23i)...Ustekinumab is a valuable additional option for patients with psoriatic arthritis in whom the response to previous non-biological disease-modifying antirheumatic drugs has been inadequate, or for those who have failed anti-TNF therapy. ..Regarding how this drug is used for the disease treated by each indication, we would like to take this opportunity to point out that within each AiArthritis disease diagnosis, there is a spectrum of disease that is dependent on many confounding factors, such as: <ul style="list-style-type: none"> - Age of the person when onset originates. While the average age of onset for AiArthritis diseases is 20 to 40 in adults, and any age in children (even at birth), onset can happen at any age. - Year the person was diagnosed. This is hugely important to consider, as those diagnosed prior to the age of biologics (late 1990's), which is a large percentage of those currently on Medicare, would not have had access to early and effective therapy. As a result, they are highly likely to have extensive damage (joints, organs, tissues), experience comorbidities (dual, triple or more autoimmune diseases, heart disease, Alzheimer's disease, dementia), and a history of operations (such as joint replacements). Given they missed the "window of opportunity" (see below), they are highly likely to require use of biologics to manage their disease for the rest of their lives (high costs of the medications for life equals high cost to Medicare). However, over recent years a new subgroup of AiArthritis diseases have emerged, called Last Onset (Psoriatic Arthritis, Rheumatoid Arthritis). See Section 1, Q29 for more details. <ul style="list-style-type: none"> - The window of opportunity: Duration of onset to diagnosis, initial treatment, treatment that works for the patient. The American College of Rheumatology (ACR) recommends early intervention with disease modifying agents as early as 6 months after onset for the best opportunity to achieve remission in people diagnosed with AiArthritis diseases. However, diagnosing these diseases rarely occurs within this time frame for a variety of factors including, but not limited to: 1) delay in detection 2) delay in referral to a specialist 3) access to specialists (health equity, lack of specialists, rural areas).
	Prescribing Information	

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Question	Sub-Question
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Response

- The average time to diagnose these diseases varies, but ranges between 1 and 9 years. Fixing the issue of early diagnosis and therapy will increase rates of remission and enable many patients to discontinue use of expensive therapies, like biologics.
- Mild, Moderate, Severe. There are also varying degrees of disease severity. Biologics are used largely to treat moderate to severe disease, which is most common. Those with severe disease are most prone to worse outcomes and comorbidities, especially if their treatment is disrupted or they are not matched with the best therapy for their unique needs early on.

Comorbidities. An estimated 50% or more of people with one AiArthritis disease will develop at least one more autoimmune/autoinflammatory disease, which happens when inflammation is uncontrolled. [1] Uncontrolled inflammation is also responsible for potentially developing heart disease, interstitial lung disease, Alzheimer's disease, and dementia. [2] [3]

- Disease complexity. AiArthritis cannot express enough that a diagnosis does not dictate how a disease manifests in any one condition. For example,

In Psoriatic Arthritis (PsA), it is possible to be diagnosed based on nail lesions and other factors, in the absence of psoriasis. However, in many cases psoriasis is a major consideration when determining the efficacy of a treatment. Furthermore, a subgroup of PsA will also experience gastrointestinal issues, at times severe, in which the doctor would determine biologic treatment based partly on what works best in diseases like Crohn's disease...Psoriatic Arthritis (PsA). As a result of data published and conference presentations that reported high-quality, evidence-based, domain-focused recommendations for medicine selection in PsA (2013-2020), the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), along with clinicians and patient research partners, revised the recommendations published in 2015. New recommendations consider treatments for the key domains of PsA: peripheral arthritis, axial disease, enthesitis, dactylitis, and skin and nail psoriasis; additional searches were performed for PsA-related conditions (uveitis and inflammatory bowel disease) and comorbidities. Individual subcommittees used a GRADE-informed approach, taking into account the quality of evidence for therapies, to generate recommendations for each of these domains, which were incorporated into an overall schema. Choice of therapy for an individual should ideally address all disease domains active in that patient, supporting shared decision-making (which also involves a Treat-to-Target/T2T approach. As safety issues often affect potential therapeutic choices, additional consideration was given to relevant comorbidities. [4] ..Viewing the attached chart, CMS can see how complex PsA is and why treatment recommendations vary, in part, based largely on disease domains. As stated in Stelara's prescribing information, this drug is recommended after failure of a TNFi, which is also recommended in 6 of the 8 domains outlined in the graphic. Complexity of disease domains, see attached chart. How do we add/cite a chart? They will read charts: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9244095/figure/Fig2/> To note, patient preferences were considered in these recommendations. Also, in keeping with our statements throughout, they also state, "Comorbidities and associated conditions may impact choice of therapy and/or guide monitoring," and "Treat, periodically re-evaluating treatment goals and modify therapy as

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Question	Sub-Question
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Response

required.”..Crohn's disease. In 2021, the American Gastroenterological Association (AGA) published new guidelines for the medical management of moderate-to-severe Crohn's disease. [5]In these, they state that biologics are the most effective drugs for the management of Crohn's and they should be used early, rather than delaying their use until after failure of mesalamine and/or corticosteroids, in patients with moderate to severe or fistulizing Crohn's disease. Of the 25 recommendation to guide treatments, the two of importance to note include:

- Anti-tumor necrosis factor (anti-TNF) agents or ustekinumab are recommended and vedolizumab is suggested as a first-line treatment.
- In patients who have previously not responded to anti-TNF agents, AGA recommends ustekinumab or vedolizumab.

Prior to the utilization of a T2T approach, the word remission was relatively unheard of for the large majority of patients living with moderate to severe AiArthritis diseases. Over the past few years, research has demonstrated when patients are treated early and have high efficacy responses to treatments - which may require working with their rheumatologist to alter therapies and types of biologic targets (i.e., stay on a TNFi, like Enbrel). .. *MoA switching to get disease under control, but not ok to switch to different drugs with the same MoA (different inactive ingredients, different method of application, etc.) ...Process of finding the right treatment (Trial and Error). In addition to all the factors previously mentioned, CMS must also consider the process it takes to find a treatment that works.* Biologics take, on average, 3 months to determine if they are working or if a patient should work with their doctor to reassess and prescribe a new therapy. (See T2T approach, Section 1, Q27). At this point, several factors can dictate if therapy can be switched, largely including access to specialists/frequency of visits and accessibility of the doctor recommended treatment on the insurance plan formulary. As a result, the average patient will try and fail 2 to 3 biologics before finding the one that works best for them. This process factors into why continuity of care is vital (once the right medication is found) and in consideration why comorbidity progression may happen... *This includes working well enough to achieve remission or, at the least if remission isn't possible, the best possible quality of life...What matters to patients. AiArthritis is the only patient organization in the world that focuses on the group of autoimmune and autoinflammatory disease inclusive of inflammatory arthritis as a major clinical component and whose leaders are all either living with the conditions or, in one case, is a caregiver for a person struggling to get diagnosed (“the undiagnosed”, a large portion of our population who represent delays in detection, referrals, diagnosis). From a patient perspective, if a drug is working well for us (we are stable), there should be no alternatives. Disrupting continuity of care when continued stability cannot be guaranteed is ethically questionable.

1. "Autoimmune Registry." How Likely are You to Have More than 1 Autoimmune Disease? Autoimmune Registry, 26 July 2022, www.autoimmuneregistry.org/newsletters/how-likely-are-you-to-have-more-than-1-autoimmune-disease. Accessed 2 Oct. 2023
2. Sangha, Pritpal S et al. “The Link Between Rheumatoid Arthritis and Dementia: A Review.” Cureus vol. 12,4 e7855. 27 Apr. 2020, doi:10.7759/cureus.7855

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Question	Sub-Question	Response
	<p>Evidence Submitted include a cost-effectiveness measure?</p> <p>What type of Evidence is shown?</p>	<p>3. Abou-Raya, Anna, and Suzan Abou-Raya. "Inflammation: a pivotal link between autoimmune diseases and atherosclerosis." <i>Autoimmunity reviews</i> vol. 5,5 (2006): 331-7. doi:10.1016/j.autrev.2005.12.006</p> <p>4. Coates, Laura C et al. "Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021." <i>Nature reviews. Rheumatology</i> vol. 18,8 (2022): 465-479. doi:10.1038/s41584-022-00798-0</p> <p>5. "New AGA Guidelines on the Medical Management of Moderate-to-Severe Crohn's Disease." <i>Gastro.org</i>, 27 May 2021, www.gastro.org/news/new-aga-guidelines-on-the-medical-management-of-moderate-to-severe-crohns-disease/.</p> <p>N</p>
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	<p>AiArthritis understands the purpose of this initial phase of data collection is, in part, to determine if there are alternatives to treatments currently covered by Medicare Part D that could be substituted to save costs to patients and the Medicare system. We also realize the goal is to establish a Maximum Fair Price (MFP), not to pull access from a medication already working well for the patient. However, we are concerned patients on Stelara - and who are stable on them - will lose access if CMS does not realize the importance of continuity of care in those living with AiArthritis diseases. For this reason, we would like to take this opportunity to explain why continuity of care is vital in this population...AiArthritis feels obligated to also mention that any price negotiations that result in a patient's loss of access to Stelara, and if stable on this treatment, could have dire results for both the patient and the healthcare system. Delayed access to treatments, including disrupting continuity of care by switching a stable patient to another treatment, can disrupt the immune response and cause unnecessary disease instability and progression (harm). ..AiArthritis diseases, which are heterogeneous (unique to individuals and subgroups). They are caused by issues within the body's immune system, which is complex and requires regulation when overactivity causes uncontrolled inflammation. [1] Therefore, people diagnosed with the same disease (i.e. rheumatoid arthritis or psoriatic arthritis), will not all respond the same way to a drug approved by the FDA to treat it. This issue is exacerbated by clinical trial design, which historically excludes people with comorbidities (which are common in our diseases) and lack demographic representation.[2] As a result, once a drug gets to market, while it may work for many patients, it equally will not work for others. So the process to find the right medication is complicated, often requiring a lengthy trial-and-error process. (See Section 1, Q27: Trial and error process...For example, a person who was diagnosed over 20 years ago, who has significant damage to their joints and has developed multiple comorbidities - such as another AiArthritis disease, heart disease, or other organ complication - experiences a different "psoriatic arthritis" journey than a person diagnosed a year ago and treated early with an effective therapy. (See Section</p>

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Question	Sub-Question
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Response

1, Q27: AiArthritis disease diagnosis, there is a spectrum of disease that is dependent on many confounding factors)...Sample of patient testimony regarding biologic efficacy and what that means to them:

"Before I was on this drug, I was struggling to maintain any real quality of life. I honestly don't know how I raised a family and pushed through the pain and fatigue for so many years. I guess I thought this was just my new normal and I'd have to live with it. When I switched rheumatologists, she suggested we switch medications and Enbrel was the one my insurance company said to try. Given I was failing the other one, I was happy to give it a whirl! WOW - in just about a month I felt better than I had in years! For some people, it may seem like small things, like I could go on walks with my husband after dinner and not have to worry about how I would get home if I walked too far. Or being able to hold my granddaughter in my arms for more than a few minutes. I've been on this drug now for over 3 years and if my Medicare plan decided to take it away from me now, I'd be devastated. I don't understand how any company without data on ME can justify forcing me to leave behind a miracle and gamble on my life."

"While I am no longer taking this drug, it was my magic bullet for years. I think due to menopause my hormones changed and it affected my immune response to the drug. I was on it for 15 years and then it stopped working. It took over 2 years to find something else that worked for me, but that trial and error process was a nightmare. I know the same biologic can work wonders for one person and do nothing for the next, so I'm grateful it worked for me as long as it did. I believe that is why I have not had joint replacements like many of my friends."

In addition to subgroups that exist among a diagnosis group (i.e., Crohn's disease and Psoriatic Arthritis), while the diseases have overlapping symptoms (classic autoimmune features, regardless of diagnosis - fatigue, low-grade fever, brain fog and gastrointestinal challenges), the differentiating symptoms vary (i.e., Crohn's disease includes abdominal pain, diarrhea, recurrent fistulas and Psoriatic Arthritis includes significant joint and enthesitis (tissue to bone) pain and usually psoriasis). ..Evidence of efficacy. Clinical trials included patients who failed or were intolerant to other medications, including a biologic, prior to STELARA®. After only one intravenous (IV) infusion of STELARA®, the majority of patients saw rapid relief from their UC symptoms in just 8 weeks, with nearly 1 in 5 achieving remission. 4 out of 10 patients were in remission at year 1 after responding to the IV induction dose and continuing treatment with STELARA®. Nearly 7 out of 10 patients had no rectal bleeding at all and also had fewer daily bowel movements at 2 years. [3] ..AiArthritis is equally impressed with another real-world effectiveness study in patients with Crohn's disease, where of 1,113 patients, 40% from a highly refractory group (meaning difficult to treat, history of failing 2 or more treatments) achieved clinical remission by 12 months. [4] ..At AiArthritis, we are led by people living with diseases and who use biologics to manage our conditions. For this reason, we feel it is important to note Ustekinumab was successful in treating patients who failed other biologics, found relief after one treatment, and after a year 45% reported remission. These statistics are phenomenal, as most patients spend months, even years finding the treatment that brings them great results. Remission is a big word in our community, a word most of us believe is not possible. Like any biologic, if a patient is stable on it, removing them and forcing them to risk instability is



Question	Sub-Question	Response
		<p>ethically questionable and inhumane. But when there is strong evidence, especially for those who are not newly diagnosed and, therefore, have less chance to achieve remission, cost in the short term seems worthwhile to improve lives and save costs over time (by not having to be on medication one day)...Statement on biosimilars. While researchers have expressed there are not significant changes in immune responses when switching from the reference product to a biosimilar, most rheumatologists in the United States (and patients, too) are still concerned any time a stable patient is switched drugs without consultation with their doctor (as many factors, as outlined elsewhere in these statements must be considered outside of one disease diagnosis). Additionally, switching can sometimes lead to an increase in total healthcare costs, which is a crucial consideration. [5] [6] ..We are also unclear how these IRA negotiations and FMP evaluations will consider biosimilars as they come to market. We are excited about biosimilars, which we hope will improve access and lower costs, but we are concerned how the pricing caps will impact their rollout....What matters to patients. Outcomes that CMS will view in literature submissions, which measure disease activity, are equally important to patients. However, disease activity measured in pain or fatigue levels, for example, cannot capture patient-specific short term and long term goals. ..Short term goals (outcomes) can include things like being able to stand in line long enough at the grocery store to check out (many patients must make numerous trips weekly to grocery shop, as they are unable to stand in long lines, walk the duration of time to shop, carry large quantities of groceries inside or put them away). Inability to buy in bulk or choosing to have groceries delivered both lead to elevated costs for the patient and their families. Often these are activities most take for granted, such as being able to hold a grandchild (due to pain) or attend a family gathering (due exhaustion and fatigue)...Long term goals (outcomes) often include the same endpoint as the treating physician - remission. As explained previously, however, currently remission is not common unless treated relatively early and with the right treatment. (See Section 1, Q27: Trial and error process)...These outcomes were chosen because they are real world needs that are often not considered in current research or, in the case of remission, are not found readily in research for those who were not treated early and effectively.</p>
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28</p> <p>Evidence Submitted include a cost-effectiveness measure?</p>	<p>N</p>
	<p>What type of Evidence is shown?</p>	

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Response to Question 29	<p>Persons with disabilities. “Persons with disabilities often experience a wide and varying range of health conditions that lead to poorer health and shorter lifespan. In addition, discrimination, inequality, and exclusionary structural practices, programs, and policies create barriers to timely and comprehensive health care, which further results in poorer health outcomes. People with disabilities who also belong to one or more other populations with health disparities fare even worse.” This is a quote taken from the September 2023 announcement by the National Institute on Minority Health and Health Disparities that people with disabilities will be designated as their own health disparity population.[1] This is, in part, due to recognition work needs to be done to better understand the complexities that lead to worse outcomes and the need for multilevel interventions. ..Elderly-onset Rheumatoid Arthritis (EORA), Psoriatic Arthritis (EOPsA). While typically people with AiArthritis diseases, like RA, experience adult onset between the ages of 20 and 40, there is a new subgroup of RA (EORA) that affects persons over the age of 60.[2] [ref] It is often characterized by acute onset and high disease activity (positive for antibodies that signal worse disease and outcomes and presence of bone erosions). As people age, bone density diminishes and the immune system weakens. Comorbidities that are common in uncontrolled AiArthritis diseases (such as heart disease, interstitial lung disease, Alzheimer's, and dementia), can also occur as one ages. This puts this subpopulation in particular risk for worse outcomes. Treatment for EORA AiArthritis would also like to point out that this phenomenon is not only occurring in RA, but also in other AiArthritis diseases, like Psoriatic Arthritis and Spondyloarthritis [3][4]..Investigating Associations Between Access to Rheumatology Care, Treatment, Continuous Care, and Healthcare Utilization and Costs Among Older Individuals. Research was conducted to examine the association between rheumatologist access, early treatment, and ongoing care of older-onset rheumatoid arthritis (RA) and healthcare utilization and costs following diagnosis. Access to rheumatologists for RA diagnosis, timely treatment, and ongoing care (continuity of care) are associated with lower total healthcare costs at 5 years. Investments in improving access to care may be associated with long-term health system savings. While this study was conducted in persons with EORA, the findings are relevant for other diseases, like Psoriatic Arthritis, where time to diagnosis and treat, as well as treatments used, are similar.[5] ...Treat-to-Target (T2T) versus Usual Care. Current consensus amongst the rheumatology community is that a T2T strategy should be used when treating people with AiArthritis diseases. (See T2T approach, Section 1, Q27). An example of usual care would consist of visiting a rheumatologist or other specialist who is not closely monitoring disease activity and who is not altering therapies regularly to achieve better outcomes...Complexities of diseases, including subgroups and disease-specific domains. As mentioned throughout our comments, our diseases themselves are complex and consist of many domains to consider when choosing a treatment. (See Section 1, Q27: Complexity of disease domains, see attached chart)...AiArthritis, an organization led by patients, would like CMS to consider the cost savings associated with a T2T approach. From personal experience, we understand the value associated with patient-rheumatologist/specialist targeted treatments (which includes more doctor visits initially, but less poorer outcomes and additional specialists treatments/comorbidity development long term). ..While the switch recommended was still in the same biologic MoA (IL-17i), any switch from a stable</p>

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Question	Sub-Question
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Response

disease state is strongly not recommended - for any reason. Even if a biologic (or biosimilar) targets the same thing there are other factors to consider, such as 1) method of application (injection needed versus pen, infusion versus injection) or 2) inactive ingredients/methods of manufacturing, which can cause an immune response. Additionally to consider, once a stable AiArthritis disease patient is pulled from a biologic treatment, it's possible if they try to go back to the original medication it will no longer be as effective. While many studies, for example with biosimilars, show switching from the reference product to a biosimilar is safe, because of patient experience and testimony within our own organization - which speaks annually with thousands of patients worldwide - we do not endorse switching a stable patient to either a different biologic (same MoA, or otherwise) or a biosimilar...Precision medicine. Precision medicine, which is the integration of clinical research and a patient's biologic makeup (biomarkers - blood, tissues), is moving quickly into the rheumatology space. As more research is done into patient subgroups, data will enable doctors (and payers) to better understand which treatments will, or will not, work best for a patient - potentially eliminating the current trial and error process and improving the chance for drug-free remission. (See trial and error process, Section 1, Q27)..AiArthritis would also like CMS to consider the following in regards to cost:.As outlined previously, neither Stelara - nor any other biologic or biosimilar - should be forced on a patient without their doctor, who is ethically obligated to treat to the unique characteristics of the patient [5] . If Stelara is the priority drug on the formulary and either 1) it is the patient's first time trying a biologic or 2) the patient is not doing well on their current biologic AND they historically have done well on anti-TNF MoA's or 3) the patient is not doing well on their current biologic AND there is no known history if they will do well, or not, or an anti-TNF drug, then it is acceptable to follow step therapy protocols. However, if 1) the patient is stable on an existing therapy or 2) the patient has tried and failed Enbrel prior or 3) the patient is known not to respond well to anti-TNF drugs, then Enbrel should not be used as a therapy forced by Medicare or other insurance plans. ..When Stelara, or any other biologic treatment, does not follow the protocol for true safety and efficacy (as outlined above), it's the onus of CMS and the insurance company to fix the system that inevitably leads to Enbrel being on the 20% highest cost list. AiArthritis understands Pharmacy Benefit Managers (PBMs) are at the root of the negotiation process that establish formularies and that transparency is required first if the system has a chance of being fixed. So we encourage CMS to support any efforts around PBM transparency and reform as the first step to solving the high cost of these drugs...The second step CMS and payers can take to lower drug prices is to understand some diseases, like AiArthritis diseases, are not conducive to one-size-fits-all treatment plan. AiArthritis understands regulations must be in place to ensure physicians and patients do not continuously and regularly select higher cost options, but we also encourage those designing and implementing these protocols to remember doctors are also ethically responsible to consider cost in their recommendations. Unfortunately, doctors are not able to exercise that ethical duty in the case of AiArthritis diseases and biologic/biosimilar therapies...What matters to patients. "Our diseases are not one-size-fits-all, so just because one person is diagnosed with a condition does not mean the rest of the world diagnosed with that same condition is going to respond the same to a treatment. This is a vital flaw in formularies and the way

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Question	Sub-Question	Response
		<p>treatments are matched to patients. Given our drugs make up 2 of 10 in the CMS high costs lists, one would think finding ways to eliminate trial and error and keep a patient stable would be the priority.”..”Regarding accessibility and cost, there are many patients on Medicare Part D that used to be on biologics and had to stop using them when they started Medicare, simply because they can no longer use the manufacturer's copay assistance program while on a government program. I think CMS needs to consider what losing access to these treatments means for their community and will be willing to work with manufacturers to find solutions that are more affordable.”</p> <p>Sugihara, Takahiko. "Treatment Strategies for Elderly-Onset Rheumatoid Arthritis in the New Era." Modern Rheumatology, vol. 32, no. 3, 2022, pp. 493-499, doi:10.1093/mr/roab087.https://academic.oup.com/mr/article-abstract/32/3/493/6430616?redirectedFrom=fulltext&login=false</p> <p>Mougui, Ahmed et al. “Characteristics of Late-Onset Spondyloarthritis: Data from the Moroccan Registry of Biological Therapies in Rheumatic Diseases.” Cureus vol. 15,5 e39100. 16 May. 2023, doi:10.7759/cureus.39100</p> <p>Caso, Francesco et al. “Late-Onset and Elderly Psoriatic Arthritis: Clinical Aspects and Management.” Drugs & aging vol. 36,10 (2019): 909-925. doi:10.1007/s40266-019-00688-3</p> <p>Barber, Claire E H et al. “Investigating Associations Between Access to Rheumatology Care, Treatment, Continuous Care, and Healthcare Utilization and Costs Among Older Individuals With Rheumatoid Arthritis.” The Journal of rheumatology vol. 50,5 (2023): 617-624. doi:10.3899/jrheum.220729</p> <p>"Health Disparities Population Designation." National Institute on Minority Health and Health Disparities, www.nimhd.nih.gov/about/directors-corner/messages/health-disparities-population-designation.html. Accessed 2 Oct. 2023.</p> <p>"Ethics of Step Therapy Investigation." AiArthritis, 2025, https://irp-cdn.multiscreensite.com/8f027529/files/uploaded/The%20Ethics%20of%20Step%20Therapy%202019.pdf. Accessed 2 Oct. 2023.</p>
	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	

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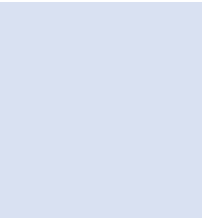
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Question	Sub-Question	Response
Question 30: Addressing Unmet Medical Needs	Response to Question 30	n/a
	Hyperlink to Citation - Additional Materials for Question 30	<ol style="list-style-type: none"> 1. "Immune System Overview." National Institute of Allergy and Infectious Diseases, www.niaid.nih.gov/research/immune-system-overview. Accessed 1 Oct 2023. 2. "Addressing Demographic Disparities in Clinical Trials." Harvard Business Review, 2021, https://hbr.org/2021/06/addressing-demographic-disparities-in-clinical-trials. Accessed 2 Oct. 2023. 3. "About Stelara." Stelara Information, www.stelarainfo.com/ulcerative-colitis/about-stelara. Accessed 2 Oct. 2023. 4. Johnson, Amanda M., et al. "Real-World Effectiveness and Safety of Ustekinumab in the Treatment of Crohn's Disease: Results From the SUCCESS Consortium." The American Journal of Gastroenterology, vol. 118, no. 2, 2023, pp. 317-328, doi:10.14309/ajg.0000000000002047. 5. Allocati, Eleonora et al. "Switching Among Biosimilars: A Review of Clinical Evidence." Frontiers in pharmacology vol. 13 917814. 24 Aug. 2022, doi:10.3389/fphar.2022.917814 6. "Talk Show Ep88." AiArthritis, www.aiarthritis.org/talkshow-ep88. Accessed 2 Oct. 2023.
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	<p>AiArthritis diseases, like psoriatic arthritis and crohn's disease, are complex diseases that require close monitoring using a Treat-to-Target (T2T) approach to achieve low disease activity, potential remission, and the best opportunity to avoid comorbidities. Continuity of care is vital for patients, yet current insurance practices disregard this need and often, as a result, patients develop complications and may require lifelong treatment. AiArthritis strongly cautions CMS against switching any patient off of Stelara , or any other biologic if their</p>



Question	Sub-Question
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	<p>Response</p> <p>disease is stable. ..While the drug under review contributes the top 20% of costs for Medicare Part D, we encourage CMS to consider other factors that lend to that position (i.e., step therapy/PBMs, placement on formularies/forced use). ..What matters to patients and their health is the most important factor to consider, so we hope CMS continues to expand their work to include patients in the negotiation process. We are concerned how the introduction of biosimilars and precision medicine will be considered as new medicines and research is introduced.</p>
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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Aimed Alliance
	Respondent Email	
	Who is completing this form?	PAO
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
	Response to Question 29	

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	

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Question	Sub-Question	Response
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	



September 28, 2023

Chiquita Brooks-LaSure
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: IRA Patient Listening Sessions

Dear Administrator Brooks-LaSure:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to express our concerns with the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions.

While we support efforts aimed at making prescription drugs more affordable for Medicare Part D beneficiaries, Aimed Alliance strongly urges the Centers for Medicare & Medicaid Services (CMS) to ensure the patient voice and perspective is valued in a genuine, long-term, and sustainable manner.

I. Background

In August 2022, Congress passed the IRA, which provided CMS the authority to directly negotiate the prices of certain prescription drugs with drug manufacturers.¹ The negotiations are limited to single source drugs, without generic or biosimilar alternatives, that have been on the market for at least 7 years, or 11 years for biologics.² On August 29, 2023, CMS published a list of 10 prescription drugs that are subject to the Medicare negotiation process. These drugs cover treatments for cardiovascular diseases, diabetes, chronic kidney disease, psoriasis, rheumatoid arthritis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.³ CMS stated these drugs were identified as the ten most expensive covered Part D drugs.

In determining the negotiated price CMS will impose, CMS stated it will consider various factors, including comparative effectiveness and impact on specific populations, such as individuals with disabilities, the elderly, terminally ill patients, children, and others; and the extent to which the drug and its alternatives address an unmet medical need.⁴ Aimed Alliance urges CMS to ensure patient and provider lived experiences are adequately valued when considering these factors and throughout this process.

¹ CMS, *Fact Sheet: Key Information on the Process for the First Round of Negotiations for the Medicare Drug Price Negotiation Program*, <https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf>

² *Id.*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*, <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>

³ *Id.*

⁴ <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>

II. Appropriately Value Patient and Provider Lived Experiences

Aimed Alliance applauds CMS for incorporating patient and provider lived experiences in the drug negotiation process. However, we urge CMS to expand the current process to ensure a wider network of patients and providers can participate, and to guarantee patient and provider voices are genuinely valued.

Internationally, several countries employ mechanisms that allow governments to negotiate drug prices with manufacturers. For example, France and Sweden base drug pricing on factors such as therapeutic value, the price of comparable treatments, and the contributions of the drug's sales to the national economy.⁵ Sweden further incorporates ethical considerations, prioritizing those with the greatest health care needs and ensuring the process upholds and respects individual human dignity.⁶ By valuing the needs of patients and providers, Sweden maintains an overall high health care satisfaction rate.⁷ In contrast, the United Kingdom, which also implements a government negotiation program, has seen reports of patients being unable to access innovative treatments that may improve their condition and quality of life due to non-patient-centered valuations.⁸ As a result of failing to appropriately value patient-perspectives on the benefits of treatments, patients in the United Kingdom also experience reduced uptake of new cancer treatments.⁹

Ultimately, while various systems have provided means to center patient-perspectives and lived experiences, not all systems genuinely value these insights in determining drug prices, ultimately impacting treatment accessibility. Aimed Alliance urges CMS to properly value the lived experiences of patients, providers, and caregivers, and recognize the benefits these treatments provide to consumer's health and quality of life.

III. Expand the Number of Listening Sessions to Ensure Diverse Representation

Under the current framework, CMS offers only one listening session for each selected prescription drug, with each session lasting less than two hours and accommodating only 20 in-person speakers. Members of the public who are not selected to speak also have the option to submit written comments.¹⁰ Aimed Alliance urges CMS to expand the number of listening

⁵ David J. Gross, Jonathan Ratner, James Perez & Sarah Glavin, *International Pharmaceutical Controls: France, Germany, Sweden, and the United Kingdom*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193451/#:~:text=New%20product%20prices%20emerge%20from,sales%20to%20the%20national%20economy>.

⁶ Global Legal Rights, *Pricing & Reimbursement Laws and Regulations 2023*, <https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/sweden>

⁷ Roosa Tikkanen, et al., *Sweden Scorecard*, <https://www.commonwealthfund.org/international-health-policy-center/countries/sweden>; Ketevan Kandelaki, *Patient-centeredness as a quality domain in Swedish healthcare: results from the first national surveys in difference Swedish health care setting*, <https://bmjopen.bmj.com/content/6/1/e009056>.

⁸ Houses of Parliament: Parliamentary Office of Science & Technology, *Drug Pricing*, https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf

⁹ *Id.*

¹⁰ CMS, *Medicare Drug Price Negotiations Program Patient-Focused Listening Sessions*, <https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions>

sessions to ensure patients, organizations, and caregivers have the opportunity to speak on behalf of their communities.

The 20 speakers selected to participate in each session are requested to address patients' day-to-day experiences living with their condition and under their treatment; the benefits and side effects of the treatments; patient access, adherence, and affordability; and any additional information the speaker considers significant.¹¹ While Aimerd Alliance believes this information is crucial for appropriately determining the negotiated prices, we are concerned that relying on 20 randomly selected speakers will not provide CMS with a comprehensive perspective on these medications and their benefits to patients, providers, and caregivers. We are also concerned that this random selection process could unintentionally exclude speakers who shed light on health equity, minority health, and other access issues.¹² Therefore, we urge CMS to expand the number of listening sessions to ensure CMS appropriately considers the broad implications and health equity considerations of these treatments; and how these price negotiations could impact access for diverse communities.

Lastly, we strongly encourage CMS to value and give due consideration to both written and spoken comments provided by patient advocacy organizations. Individuals with chronic illnesses such as multiple sclerosis and inflammatory bowel disease (IBD) frequently experience social stigma, rejection, and workplace discrimination resulting from their condition.¹³ For instance, one study found that out of 105 patients with IBD, 84 percent reported experiencing stigma associated with their condition.¹⁴ Consequently, it is critical to recognize that some individuals with chronic conditions may not feel comfortable discussing their health, treatments, and challenges openly. As a result, they often rely on advocacy organizations to share their stories, perspectives, and experiences.

IV. Conclusion

In conclusion, we sincerely appreciate the opportunity to provide feedback on the IRA process and CMS's efforts to ensure the voices of patients, providers, and caregivers are at the forefront of this process. Please contact us at policy@aimedalliance.org if you have any additional questions.

Sincerely,
Ashira Vantrees
Counsel

¹¹ *Id.*

¹² Khiara Bridges, *Implicit Bias and Racial Disparities in Health Care*, https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/racial-disparities-in-health-care/

¹³ Valerie A Earnshaw, Diane M. Quinn & Crystall L. Park, *Anticipated stigma and quality of life among people living with chronic illnesses*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3644808/>

¹⁴ Marco Vinenzco Lenti, et al., *Stigmatization and resilience in inflammatory bowel disease patients at one-year follow up*, <https://www.frontiersin.org/articles/10.3389/fgstr.2022.1063325/full>

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Alliance for Transparent and Affordable Prescriptions
	Respondent Email	
	Who is completing this form?	OTH
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
	Response to Question 29	

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	

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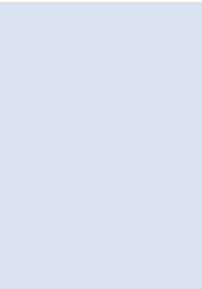
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Question	Sub-Question	Response
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	<p>The Alliance for Transparent and Affordable Prescriptions (ATAP) Action Network thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide feedback on implementation of the Medicare Drug Price Negotiation Program (“the Program”) and the mechanics of the new “maximum fair price” (MFP) paradigm...ATAP was created in 2017 with a mission to address prescription drug costs and patient access to affordable treatment by regulating PBM practices and reforming the drug industry through educational outreach and grassroots advocacy initiatives at both the state and federal levels. Driven by the reality that many patients struggle to afford their medications, the physician and patient advocacy organizations joined to expose the abusive practices of PBMs...We will limit our comments to highlighting the potential formulary impacts of the Program, and suggesting a solution that will mitigate those impacts. The Inflation Reduction Act requires that Part D plans cover drugs with an MFP. Presumably, the goal of this coverage requirement was to maximize the number of beneficiaries who can access the MFPs and thus benefit from MFP-level cost-sharing. However, the statute does not prohibit utilization management on MFP drugs, nor does the statute specify where an MFP drug must be placed on formulary. As we've seen in the commercial market, “coverage” becomes an empty word when the covered medication is subject to Kafkaesque utilization management protocols that render it functionally non-covered...Since the MFP mechanism will not apply to drugs with generics/biosimilars, this issue will become especially important for disease states in which much of the pharmaceutical competition is among brands. If drugs A, B, and C all treat rheumatoid arthritis, but only Drug A has an MFP, the PBMs may prefer options B and C, because these will present income potential for them. Already, plans use utilization management to drive beneficiaries to the drug with the highest rebate potential, which means that beneficiaries may be pushed to high list price options over MFP options...Unless CMS controls for this dynamic, a smaller number of beneficiaries will benefit from MFP- based cost-sharing than the agency and the law's drafters might hope. To ensure that the statutory coverage requirement realizes its full potential, we urge CMS to prohibit any utilization management on MFP drugs. The stated goal of utilization management is to drive down costs, but the establishment of an MFP will greatly reduce the need to control costs via utilization controls on selected drugs. A regulatory prohibition on utilization management for MFP drugs should not result in increased costs. In fact, such a prohibition could result in prescribers and patients choosing MFP options over non-MFP options when clinically appropriate, driving program spend towards the lowest-cost option and maximizing the reach and impact of the MFP program in Medicare...In addition, we want to urge CMS to exercise particular caution with regard to medications that have both self-administered and provider-administered formulations. Stelara, which is on the list of the first ten Part D drugs selected for the Program, is an example of such a medication. Already, beneficiaries who need the provider-</p>



Question	Sub-Question
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	<p>Response</p> <p>administered version are unable to access that version, since it has been placed on the Self-Administered Drug Exclusion list. In the CY 2024 Medicare Physician Fee Schedule proposed rule, CMS issued a request for information to determine whether the process surrounding the SAD Exclusion list requires changes, in order to protect access for those beneficiaries who, for clinical, socioeconomic, or other reasons, need access to the provider-administered version of a medication. We urge CMS to avoid exacerbating that existing access crisis as it establishes MFPs for Part D medications that also have a provider- administered formulation...In closing, we want to reiterate our appreciation for the opportunity to provide input as CMS implements this new, complex program, and we hope that you will consider us a resource on the issues discussed herein.</p>
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Public E2 Submission

IPAY: 2026



Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Chronic Care Policy Alliance
	Respondent Email	
Question 27: Prescribing Information	Who is completing this form?	PAO The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public. ..As CMS weighs information on how this product is prescribed and factors that information into the negotiation process, CMS should ensure that the negotiated price continues to support the patients using the product and their current usage. Patients using the product off-label or in different doses than the label should continue to have the same access after the negotiation process. Additionally, ensuring that the negotiation does not spur greater restrictions to access or utilization management, is also important to patients.
	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public...As CMS weighs information on the therapeutic impact and comparative effectiveness of this product, it is paramount that CMS recognize that individual patients may experience substantial benefit from a product that may not be apparent in aggregated data. Because of this, as CMS considers how this area factors into the overall price negotiation, CMS should ensure a negotiated price reflects the value the product provides to each unique patient. CCPA believes it is important that the incentives to continue developing treatments for chronic diseases be preserved, and it is important to reward the value treatments bring to patients.

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Question	Sub-Question	Response
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28</p> <p>Evidence Submitted include a cost-effectiveness measure?</p>	N
	What type of Evidence is shown?	
Question 29: Comparative Effectiveness on Specific Populations	Response to Question 29	<p>The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public...Patients with chronic diseases all have their own unique experiences – in considering comparative effectiveness, CMS should weigh equally the experiences of individuals the same as measurements of experiences of specific populations – in a way that elevates all voices, instead of letting larger voices outweigh single patients. CCPA also encourages CMS to take into account populations that may be uniquely adversely affected by negotiation, such as specific patient populations that may face new utilization or formulary restrictions. In this way, CMS can ensure that it pursues a patient-centered approach.</p>
	Hyperlink to Citation - Additional Materials for Question 29	
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29</p> <p>Evidence Submitted include a cost-effectiveness measure?</p>	N

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Question	Sub-Question	Response
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	The Chronic Care Policy Alliance (CCPA) is a network of advocates focused on issues affecting patients living with chronic conditions. While we will let other disease-specific organizations offer their detailed perspectives on this drug, CCPA wishes to convey its views on how CMS should use the information gathered from the public...CMS should ensure that its negotiation process on this product does not disadvantage any patient with an unmet medical need. Specifically, CMS should guard against the results of negotiations undercutting research into the product that may meet other unmet medical needs or may negatively impact the development of other products focused on unmet medical needs.
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Crohn's & Colitis Foundation
	Respondent Email	
	Who is completing this form?	PAO
Question 27: Prescribing Information	Prescribing Information	Indicated for use in adult patients wiht moderately to serverely active Chron's disease or ulcertative colitis.
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	Included in attached communication.
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
	Response to Question 29	Incuded in attached.

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
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Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	

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Question	Sub-Question	Response
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	

October 2, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 212441

RE: Medicare Drug Price Negotiation Program: Consideration for Selected IBD Medications

Dear Administrator Brooks-LaSure:

The Crohn's & Colitis Foundation appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Medicare Drug Price Negotiation Program. The guidance begins to put in place provisions of the Inflation Reduction Act (IRA) that are of critical importance to Medicare beneficiaries – access to affordable treatments.

The Crohn's & Colitis Foundation is a non-profit, volunteer-fueled organization dedicated to finding cures for Crohn's disease and ulcerative colitis and improving the quality of life of children and adults affected by these diseases. Crohn's disease and ulcerative colitis are chronic, degenerative autoimmune diseases collectively known as inflammatory bowel disease (IBD). 1 in 100 Americans suffer from IBD. If not properly treated, IBD causes pain and a diminished quality of life, and can eventually lead to malnutrition, cognitive impairment, repeated hospitalizations, multiple surgeries, or even death.

The Foundation Commends CMS for its continued efforts to reduce financial burdens on patients. While implementing this new program, it will be critical that CMS work with patients and their representatives to support patient choice and access to needed medications.

IBD patients have benefitted greatly from the introduction of biologic medications that promote and extend disease remission. Biologic therapies such as Stelara offer a distinct advantage in IBD treatment because their mechanisms of action are more precisely targeted to the factors responsible for IBD. Unfortunately, these medications are quite expensive, and biosimilars have been slow to come to the market.

The affordability of therapies remains a serious obstacle for many IBD patients. Even with Medicare coverage, beneficiaries who need access to innovative drugs may find their out-of-pocket costs running into thousands of dollars each year. For these IBD patients, skipping treatments, or abandoning prescribed drug therapies because of cost can have serious health consequences. Other patients go into significant debt, even bankruptcy, to pay for their treatments.

We offer some general recommendations for ensuring that patients receive the most benefit of the price negotiation program as well as specific comments in direct response to questions CMS has raised in different sections of the draft.

The Importance of Patient Guardrails

Affordability and access are critical for ensuring that IBD patients receive the best treatment at the optimal time. As CMS moves forward with implementation of the Medicare Drug Price Negotiation Program, we urge you to carefully balance the need to lower the cost of drugs offered through Medicare with ensuring patient access to drug therapies. To this end, we ask you to consider several patient “guardrails” that could help to achieve that goal.

Monitoring and Reporting

The Crohn’s and Colitis Foundation encourages CMS to carefully monitor and publicly report on the implementation of the negotiation process as it pertains to beneficiary access and cost, specifically:

- We urge CMS to ensure that Medicare enrollees share the savings achieved through negotiation. CMS should ensure that enrollees’ cost sharing is based on the Medicare negotiated rate. In no case should patients pay more out-of-pocket for a drug that is subject to negotiation than they were paying previously. Absent clear directive from CMS, a drug that is subject to negotiation could be placed on a higher formulary tier (for example, a non-preferred brand) and enrollees could pay higher cost-sharing as a result.
- While the guidance document pertains to the Medicare negotiation process solely for Part D covered drugs, we also recognize that CMS has a vested interest in adopting similar rules for the Part B program. Therefore, we urge CMS to monitor the prescribing patterns of drugs subject to negotiation to determine whether patterns are impacted by the negotiation process. If prescribing patterns fall beyond a statistically significant measure, we urge CMS to conduct independent analysis to determine why prescribing has changed. This will likely be more of an issue with infused medications covered by Part B, given the direct impact of physician reimbursement. Therefore, we recommend that CMS put in place monitoring processes for both programs to ensure continued beneficiary access.
- CMS should monitor plan formularies to determine the extent to which plans are using utilization management tools to steer patients to particular medications. For patients who have found a specific drug that works for treating their IBD, being steered towards another – potentially less effective drug – would be detrimental. As Part D plans will bear more risk under the IRA’s Part D benefit redesign, plans will have a financial incentive to steer beneficiaries toward a drug with the lowest price the plan is able to negotiate. While it is possible that negotiated drugs would represent the lowest price, non-negotiated drugs could actually cost less due to rebate dynamics. It is possible that Part D plans could steer beneficiaries toward or away from negotiated drugs and that they may impose barriers (such as more rigorous prior authorization or step therapy requirements) on others in the class.

Evidence about Therapeutic Alternatives for the Selected Drug

To determine the maximum fair price of a selected drug, CMS is required by law to consider evidence about alternative treatments. This includes the comparative effectiveness of the selected drug and its therapeutic alternatives, and their effects on specific populations.

The Crohn's & Colitis Foundation supports comparative effectiveness research because it provides clinicians with information regarding the relative clinical effectiveness of a given intervention and potential differences in side effects. However, we strongly oppose the use of quality-adjusted life years to make coverage determinations or to set patient cost-sharing. Doing so fails to consider the value an individual may place on the quality of life provided to them from a given treatment.

We encourage CMS to give credence to input from organizations with expertise in IBD treatments, to include the patient perspective. CMS should consider health outcomes such as remission, effects on disease progression, and improvements in performing daily tasks when comparing a selected drug to therapeutic alternatives. We also encourage CMS to use both patient-reported outcomes and patient experience data. Patients have first-hand knowledge of the effectiveness of a treatment, as well as the impact on their quality of life. As many IBD patients receive off-label treatment, it is particularly important for our patients that CMS considers whether a selected drug fills an unmet medical need through its or off-label use.

Exclusions from Negotiation Process

Under the new law, negotiation is limited for those drugs where there is a high likelihood that a biosimilar will be licensed and marketed in the next two years. The Crohn's & Colitis Foundation has been a staunch supporter of bringing more biosimilars to market. Biosimilars hold the promise of both expanding options for IBD patients and lowering costs for their treatments. We urge CMS to monitor the impact of price negotiation on access and innovation in the biosimilar market.

The Crohn's & Colitis Foundation is particularly concerned about adverse market interferences such as limited-supply agreements¹ on CMS's price negotiation program. We encourage CMS to require robust disclosure of material facts impacting a product's negotiation eligibility, and to disclose those facts publicly. We believe these steps are needed to promote transparency as well as the integrity of the negotiation process.

Monitoring Access to the MFP

The Crohn's & Colitis Foundation supports CMS' intent to ensure information about the maximum fair price for selected drugs is available to eligible individuals, pharmacies, mail order services, and other dispensers. Transparency will be key to overall success of the negotiation program.

We support CMS's proposal to publish the information on its website and recommend that it be done in an easy to read, easy to access, consumer-friendly format. We also recommend that CMS

¹ Gabriele SME, Feldman WB. The Problem of Limited-Supply Agreements for Medicare Price Negotiation. *JAMA*. Published online September 15, 2023. doi:10.1001/jama.2023.17208

update the Medicare Plan Finder with information for those drugs that are subject to price negotiation. In reviewing Part D plan formularies, CMS should ensure that enrollees' cost sharing is based on the Medicare negotiated rate. We further suggest CMS consider other avenues consumers generally use to get information on coverage including:

- the Medicare toll free line and call center;
- insurance plan websites;
- pharmacies and pharmacy applications;
- patient navigators; and
- patient advocacy organizations.

We support CMS' proposal to establish a process by which beneficiaries can report violations. This system should be easy to use – such as a toll-free number or an online notification system – and widely publicized. We urge CMS to set a time limit – no more than 48 hours – for responding to beneficiaries reporting violations and guidance as to the steps they should take. CMS should also report the number of complaints it receives and the number of complaints which resulted in CMS action. Finally, we urge CMS to consider creating an Ombudsman that serves as a direct point of contact for beneficiaries for these issues.

Conclusion

The Crohn's & Colitis Foundation appreciates the opportunity to provide input into the implementation of the new prescription drug price negotiation program. Please do not hesitate to contact Erin McKeon, Associate Director, Federal Advocacy if you or your staff would like to discuss these issues in greater detail. She is reachable via e-mail at emckeon@crohnscolitisfoundation.org.

Sincerely,



Laura Wingate
Executive Vice President, Education, Support, & Advocacy
Crohn's & Colitis Foundation

October 2, 2023

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Administrator
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Department of Health and Human Services
7500 Security Blvd
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Sincerely,



Laura Wingate
Executive Vice President, Education, Support, & Advocacy
Crohn's & Colitis Foundation

Public E2 Submission

IPAY: 2026



Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	
	Respondent Email	
	Who is completing this form?	PAT
Question 27: Prescribing Information	Prescribing Information	I take Stelara for Crohn's Disease. I started with a loading dose by IV infusion. Then, every eight weeks I take a subcutaneous injection as a maintenance dose.
	Evidence Submitted include a cost-effectiveness measure?	D
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	Stelara is the fourth biologic drug I have been prescribed in the last 13 years. I have been on Humira, Entyvio, Renflexis, and now Stelara. My body builds up antibodies to these biologic drugs so I have to switch to new therapies after 3 to 5 years on a biologic. Stelara costs at least \$24,827.00 every 8 weeks. There are no biosimilars available for Stelara.
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
	Response to Question 29	As a patient, I don't have information on this subject.

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	Price of Stelara per Good RX.
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	



Question	Sub-Question	Response
Question 31: Patient and Caregiver Experience	Response to Question 31	<p>In July 2022 my Crohn's Disease was flaring. I was on Entyvio, but it had stopped working. My Gastroenterologist prescribed Stelara. My insurance company required a prior authorization. The insurance denied coverage. This started a 7 month long battle to get Stelara approved. In the meantime, I needed to fight the inflammation in my intestines. My G.I. prescribed an 8 week course of Prednisone. Because of the insurance battle, I was stuck on Prednisone for 7 months. There was no alternative. ..I also have type 2 diabetes. A side effect of Prednisone is increased blood sugars. I was prescribed insulin for the first time in my life. The sugar levels were very high and did not get under control until February 2023 to when the Prednisone was finally discontinued. ..In October 2022 the insurance company insisted that I go on Renflexis, a biosimilar of Remicade. I did for 4 months. It had no effect on my Crohn's flare. I developed antibodies to it immediately...In December 2022 I suffered a partial bowel obstruction and was hospitalized. ..Finally, Stelara was approved in January 2023.</p>
Question 32: Executive Summary	Response to Question 32	

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IPAY: 2026



Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	National Psoriasis Foundation
	Respondent Email	
	Who is completing this form?	PAO
Question 27: Prescribing Information	Prescribing Information	No
	Evidence Submitted include a cost-effectiveness measure?	N
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	<p>The extreme heterogeneity of psoriatic disease makes physician and patient access to the full range of therapies particularly important given that a treatment that may work for one may fail for another and because patients often cycle through a number of treatments during their lifetime. Therefore, for many individuals living with psoriatic disease, therapeutic alternatives may be limited, and may require access to pharmaceuticals that may otherwise be more rare in the community. Only when physicians are able to access all the tools in their treatment toolbox will they be able to provide individual patients with the care that will maximize their health outcomes. ..New systemic treatments, including biologics like ustekinumab, have provided many patients with an effective therapy for the first time in their lives. In fact, today many people with psoriasis are able to achieve a level of clearance never before possible. Biologics have also opened a new world of combination therapies, being used alongside systemic treatments, phototherapy and/or topical treatments. .It is important for patient communities to have access to a broad array of treatment options. Each patient is unique in the way they respond to therapy, and there is no 'one size fits all' approach. Stable patients should not be switched to different treatments, unless prescribed by their physician or where the alternative is a generic or biosimilar. Non-medical switching or payer mandated switching of patients can be dangerous because it exposes the patient to the risk of disease progression or return, and the patient may not be able to return to the treatment that was working for them without experiencing a loss of response. Switching patients may destabilize their health, and patients may develop immunogenicity to the treatment</p>

Public E2 Submission

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Question	Sub-Question	Response
		<p>that was working for them. It is critical to ensure the treating physician and patient are informed of any switches with ample time to appeal as necessary. Stable patients should not be exposed to increased drug cost sharing because they were unwilling to switch treatments. ..In a recent meta-analysis, ustekinumab was reported to be inferior on the basis of PASI-90 at 16 weeks to seven other therapeutics (Armstrong 2020), suggesting that while the therapeutic selected for negotiation by CMS retains a clinical role in the treatment of psoriatic disease, it may not be associated with best outcomes. With respect to the position of the negotiated therapies, this data has been replicated in a systematic review of 179 studies in which the authors concluded that infliximab, bimekizumab, ixekizumab, and risankizumab represented the most effective options for achieving PASI-90 in moderate to severe psoriasis. (Sbidian, 2023). Further data support that ixekizumab and risankizumab are most associated with durable positive outcomes at 1 year, specifically PASI-100 and PASI-90 (Blauvelt 2022). Additional data favor risankizumab, guselkumab, brodalumab and ixekizumab for lower number to treat relative to PASI goals (Leonardi, 2022). ..Although population level data may not favor ustekinumab in typical cases, it may still have an important role in individual circumstances (see question 29). Thus, the NPF position is that all therapeutic decisions should be made by a patient's health care provider in the context of the patients individual needs, and that therapies prescribed for a patient should be accessible to the patient. It should, however, be acknowledged that the most recent data, as provided above, suggest that as a population CMS should consider that any economic pressure that favors ustekinumab, may be associated with less therapeutic potential, and thus place CMS at risk for health care costs related to the unmet therapeutic needs.</p>
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28</p> <p>Evidence Submitted include a cost-effectiveness measure?</p> <p>What type of Evidence is shown?</p>	
Question 29: Comparative Effectiveness on Specific Populations	Response to Question 29	<p>The NPF is concerned that IRA implementation and Medicare negotiations could severely impact care for those most in need. For example, formulary design may change, which could lead to utilization management protocols that destabilize patients with ongoing treatment or further delay access to needed prescriptions. This has the possibility of impacting specific populations, including: ..Rural populations: .. Utilization management, including step protocols and switching stable patients can affect individuals in rural areas disproportionately because these practices frequently result in the need for the individual to see their doctor or medical team</p>

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more frequently. .- Less access to internet may impede a patient's ability to appeal an adverse coverage determination. .- Less access to specialty practices may impact whether the physician pursues an appeal of an adverse coverage determination. ..Underserved, marginalized and poorer communities: .- Patients with less voice and fewer resources, such as underserved, marginalized, poorer individuals, and individuals who rely on others for advocacy, may be more at risk for delays in getting their medications (Chandra 2023). .- Resource poor areas may offer less access to specialty practices which impacts whether the patient has a provider with the additional staff needed to pursue an appeal of an adverse coverage determination (Winter 2019)..- Less education exacerbates health disparities because the individual would have a harder time navigating the appeals process. .- Less access to internet may impede a patient's ability to appeal an adverse coverage determination. ...Populations living with obesity: .- IL-12/23, such as ustekinumab, are associated with increased odds of achieving treatment outcomes among patients with obesity or a history of diabetes (Enos 2022). Obesity itself, may be more prevalent in psoriatic disease populations (eg., Queiro 2019, Lonnberg 2016, Eder 2017). Emerging basic science also suggests that obesity may itself alter treatment responses in inflammatory disease (eg., Bapat 2022), suggesting that further study of immune modifying drugs in obese populations may be warranted .. Pediatric populations.- ustekinumab remains recommended in relevant guidelines for treatment of pediatric psoriasis. The Joint American Academy of Dermatology and National Psoriasis Foundation guidelines for management and treatment of pediatric psoriasis support usage etanercept in pediatric populations, citing level I evidence (Menter 2020). ..Comorbid immune disorders .- Patients with inflammatory bowel disease may respond favorably to drugs such as infliximab, adalimumab, and ustekinumab which can be effective for IBD in addition to psoriasis. Other drugs, such as etanercept and anti IL-17 therapies, are only recommended with caution as they may aggravate the IBD (Whitlock 2018). Bordon, Y. Obesity amplifies TH17-type pathology in atopic diseases. Nat Rev Immunol 22, 274-275 (2022). <https://doi.org/10.1038/s41577-022-00721-4>

Association of Black Cardiologists, Inc. "Identifying How Prior Authorization Impacts Treatment of Underserves and Minority Patients," (Winter 2019)

Whitlock SM, Enos CW, Armstrong AW, Gottlieb A, Langley RG, Lebwohl M, Merola JF, Ryan C, Siegel MP, Weinberg JM, Wu JJ, Van Voorhees AS. Management of psoriasis in patients with inflammatory bowel disease: From the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol. 2018 Feb;78(2):383-394. doi: 10.1016/j.jaad.2017.06.043. PMID: 29332708.

Queiro, Rubén et al. "Obesity in psoriatic arthritis: Comparative prevalence and associated factors." Medicine vol. 98,28 (2019): e16400. doi:10.1097/MD.00000000000016400

Menter, A., et al. (2020). "Joint American Academy of Dermatology 2013; National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients." J Am Acad Dermatol 82(1): 161-201.

Lonnberg, A. S., et al. (2016). "Association of Psoriasis With the Risk for Type 2 Diabetes Mellitus and Obesity." JAMA Dermatol 152(7): 761-767.

Hyperlink to Citation -
Additional Materials for
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Question	Sub-Question	Response
		<p>Enos CW, Ramos VL, McLean RR, Lin TC, Foster N, Dube B, et al. Comorbid obesity and history of diabetes are independently associated with poorer treatment response to biologics at 6 months: A prospective analysis in Corrona Psoriasis Registry. <i>Journal of the American Academy of Dermatology</i>. 2022;86(1):68-76. Epub 2021/07/14. doi: 10.1016/j.jaad.2021.06.883. PubMed PMID: 34256035.</p> <p>Eder, L., et al. (2017). "The Association Between Obesity and Clinical Features of Psoriatic Arthritis: A Case-control Study." <i>J Rheumatol</i> 44(4): 437-443.</p> <p>Chandra, Amitabh, and Benedic Ippolito. "What Does the Inflation Reduction Act Mean for Patients and Physicians?" <i>NEJM Catalyst Innovations in Care Delivery</i>, vol. 4, no. 10, 20 Sept. 2023, https://doi.org/10.1056/cat.23.0138.</p>
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
Question 30: Addressing Unmet Medical Needs	What type of Evidence is shown?	
	Response to Question 30	<p>NPF reemphasizes our response from Q28: The extreme heterogeneity of psoriatic disease makes physician and patient access to the full range of therapies particularly important given that a treatment that may work for one may fail for another and because patients often cycle through a number of treatments during their lifetime. Therefore, for many individuals living with psoriatic disease, therapeutic alternatives may be limited, and may require access to pharmaceuticals that may otherwise be more rare in the community. Only when physicians are able to access all the tools in their treatment toolbox will they be able to provide individual patients with the care that will maximize their health outcomes.</p> <p>Sbidian E, Chaimani A, Guelimi R, Garcia-Doval I, Hua C, Hughes C, Naldi L, Kinberger M, Afach S, Le Cleach L. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. <i>Cochrane Database Syst Rev</i>. 2023 Jul 12;7(7):CD011535. doi: 10.1002/14651858.CD011535.pub6. PMID: 37436070; PMCID: PMC10337265.</p> <p>Leonardi CL, See K, Burge R, Sun Z, Zhang Y, Mallbris L, Garrelts A, Warren RB. Number Needed to Treat Network Meta-Analysis to Compare Biologic Drugs for Moderate-to-Severe Psoriasis. <i>Adv Ther</i>. 2022 May;39(5):2256-2269. doi: 10.1007/s12325-022-02065-w. E</p>
	Hyperlink to Citation - Additional Materials for Question 30	

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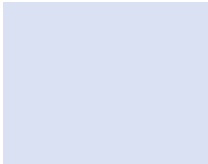


Question	Sub-Question	Response
	<p>Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30</p> <p>Evidence Submitted include a cost-effectiveness measure?</p> <p>What type of Evidence is shown?</p>	<p>Blauvelt A, Gooderham M, Griffiths CEM, Armstrong AW, Zhu B, Burge R, Gallo G, Guo J, Garrelts A, Lebwohl M. Cumulative Clinical Benefits of Biologics in the Treatment of Patients with Moderate-to-Severe Psoriasis over 1 Year: a Network Meta-Analysis. Der</p> <p>Armstrong, April W et al. "Comparison of Biologics and Oral Treatments for Plaque Psoriasis: A Meta-analysis." JAMA dermatology vol. 156,3 (2020): 258-269. doi:10.1001/jamadermatol.2019.4029</p>
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	<p>The extreme heterogeneity of this disease makes physician and patient access to the full range of therapies particularly important given that a treatment that may work for one may fail for another and because patients often cycle through a number of treatments during their lifetime. Only when physicians are able to access all the tools in their treatment toolbox will they be able to provide individual patients with the care that will maximize their health outcomes. ..While the goal of reducing costs to the healthcare system is laudable, we caution CMS to be on guard against creating environments in which prescribing behaviors are influenced inappropriately by reimbursement, which may itself be indirectly a function of drug pricing. The pharmaceutical agents under CMS review have a strong history in the management of psoriatic disease. The NPF position is that they should neither be incentivized for prescription based on cost alone, nor eliminated from the list of approved therapies available to our patient community. There is, however, a danger that lower pricing of etanercept could result in non-medical switching/payer mandated switching including fail first policies. Recent systematic reviews assess ustekinumab with lower likelihood of achieving satisfactory or durable PASI scores than other available therapies. Given this, CMS should further consider whether changes in prescribing habits might be associated with less favorable disease management, and thus negate the apparent</p>

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savings conferred by negotiation. ..On behalf of National Psoriasis Foundation, thank you for your consideration of these comments which we hope will positively inform this review. We invite you to call upon us, our Medical Board, and our patient community as you move forward.

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Pharmaceutical Care Management Association (PCMA)
	Respondent Email	
	Who is completing this form?	TRD
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure?	
Question 28: Therapeutic Impact and Comparative Effectiveness	What type of Evidence is shown?	
	Therapeutic Impact and Comparative Effectiveness	<p>The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments regarding the therapeutic alternatives for Ustekinumab. Our members help administer the Part D prescription drug benefit on behalf of many Part D plan sponsors, and a central component of that function is the identification of therapeutic alternatives to develop comprehensive prescription drug formularies consistent with applicable statutory, regulatory, and clinical requirements, including ensuring formularies are not discriminatory...In general, while we understand that CMS cannot disclose the specifics of their negotiations with manufacturers of selected drugs, we believe the public is best served by CMS disclosing as much about this process as possible, and otherwise aligning its methodology for selecting therapeutic alternatives with how Part D plans select therapeutic alternatives. Our comments focus on emphasizing the differences between identifying therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program, and the role that the identification of therapeutic alternatives plays under the Medicare Part D program's formulary standards and enrollee communication requirements. PCMA has three main points...1. As a general principle, CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for the Part D program. ...2. CMS should clarify in an HPMS memo to Part D plans that CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program will not impact the agency's existing approach towards evaluating Part D formulary design for compliance with Part D formulary requirements...3. CMS</p>

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should clarify in an HPMS memo that Part D plans retain discretion on how to communicate therapeutic alternatives to enrollees, and that CMS's identification of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program will not affect these enrollee communications...We discuss these issues in more detail below...I. CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for their formulary submissions. ..Currently, Part D plan sponsors consider a variety of factors when identifying therapeutic alternatives for their formulary submissions, including but not limited to (i) clinical effectiveness, (ii) safety, (iii) price, (iv) availability, and (v) patient preferences. Importantly, these factors are considered within a regulatory framework that imposes certain overarching formulary requirements. ..First, Part D plans must ensure that their formulary designs are nondiscriminatory. CMS considers several criteria when assessing whether a formulary is nondiscriminatory. CMS may presumptively approve formulary designs which align with the United States Pharmacopoeia's (USP) Medicare Model Guidelines (MMGs) based on the view that the MMGs reflect a scientifically and-clinically-based taxonomy developed by an independent expert body without a vested financial interest in the Part D program. The MMGs are also important because they provide a guiding framework for Part D plans to use when determining therapeutic alternatives. The MMGs group drugs into categories and classes. These categories and classes generally encompass the universe of potential therapeutic alternatives for a given medical condition. This means that Part D plans can use the MMGs to identify the range of therapeutic alternatives to consider when developing their formularies...Second, Part D plans must provide an adequate formulary, which among other things, means including at least two Part D drugs within a particular category or class of Part D drugs. This minimum formulary standard helps ensure a wide range of treatment options for enrollees, even if they have complex or rare medical conditions. Additionally, this requirement promotes patient choice and competition among drug manufacturers because the ability for patients to access alternative treatments incentivizes drug manufacturers to lower prices and innovate. The requirement to include at least two drugs per category or class helps to ensure that patients with a given medical condition have at least two formulary treatment options available to them, even if there are few therapeutic alternatives. This requirement is important because it prevents Part D plans from excluding entire categories or classes of drugs from their formularies...Third, Part D plans must consider cost sharing in the development of formularies. For example, CMS could raise concerns about formularies that place drugs on high cost-sharing tiers without placing therapeutic alternatives in preferable positions. CMS has also expressed concerns about "adverse tiering" where a plan sponsor assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high-cost medical condition to a high cost-sharing tier. In short, Part D plans must consider the enrollee's share of costs for a particular drug when considering therapeutic alternatives...PCMA encourages CMS to identify therapeutic alternatives for the Medicare Drug Price Negotiation Program in the same way that Part D plans do for their formularies. This would ensure consistency in process across two closely related programs and avoid introducing multiple, confusing standards for the same underlying definitional term. At the very least, aligning

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	<p>the selection of therapeutic alternatives under the Medicare Drug Price Negotiation Program with Part D formulary submissions would give Part D plans some assurance that CMS's assessment of their formulary submissions will not be affected by CMS's own process of selecting therapeutic alternatives...II. CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program should not compromise the agency's evaluation of the adequacy of Part D plan formulary design, ensuring that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs...PCMA acknowledges that CMS's identification of therapeutic alternatives under the Medicare Drug Price Negotiation Program is required by law and essential for successful drug pricing negotiations. As stated above, we urge CMS to attempt to align its selection of therapeutic alternatives with how Part D plans select therapeutic alternatives...That being said, it is important to recognize that the exercise of selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program and the Part D program, while overlapping in some areas, are ultimately distinct. Selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program requires unique considerations that are not fully applicable to how Part D plans identify and leverage therapeutic alternatives for formulary development. Accordingly, we do not expect CMS to perfectly align itself with Part D plan sponsor methodologies for selecting therapeutic alternatives. ..First, therapeutic alternatives are a statutory feature of the Medicare Drug Price Negotiation Program. CMS selects therapeutic alternatives when negotiating pricing for selected drugs because the statute requires the agency to do so. Even if the statute did not require CMS to identify therapeutic alternatives, CMS would likely need to do so because it supports the agency in carrying out its statutory mandate to negotiate a "maximum fair price" (MFP) with manufacturers. Importantly, the MFP applies in a vacuum without regards to affordability and relative competitiveness with other drugs that a beneficiary may access...By contrast, while Part D plans are required to select therapeutic alternatives for formulary submissions, Part D plans select therapeutic alternatives based on a delicate balance between clinical comparability, cost-effectiveness, and beneficiary access. Unlike CMS, which is required to focus on a single drug in isolation when assessing therapeutic alternatives, Part D plans, PBMs, and their pharmacy and therapeutics (P&T) committees are tasked with developing comprehensive formularies that holistically meet the complex needs of their enrollees. Part D plans must, already, cover selected drugs on their formularies under the statute, and CMS's interpretation worryingly suggests that such coverage may also involve a preferred status designation. Additional indirect restrictions on formulary design stemming from CMS's evaluation criteria under the Medicare Drug Price Negotiation Program could significantly hamper Part D plans' ability to offer competitive plan designs. In light of the comprehensive considerations that Part D plans must consider in developing formularies, CMS must ensure plans retain flexibility to adequately weigh all of these factors when developing formularies, including identifying therapeutic alternatives...Second, CMS's selection of therapeutic alternatives is a one-time event, done solely to determine the MFP for a selected drug. Once the MFP is determined, the drug's therapeutic alternatives play no further role in how Medicare beneficiaries access the selected drug...In contrast, a Part D plan sponsor's selection of therapeutic alternatives is used in multiple ways, including formulary design, coverage</p>
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		<p>determination, tiering exceptions, and Part D appeals. This means that Part D plans must carefully consider all potential scenarios in which their selection of therapeutic alternatives may be challenged...Third, CMS's identification of therapeutic alternatives for purposes of the Drug Price Negotiation Program is nonpublic. CMS indicates in the Revised Guidance for the Medicare Drug Price Negotiation Program that the agency will not unilaterally disclose any information pertaining to its negotiations with manufacturers, including the therapeutic alternatives identified for such negotiations. As a result, Part D plans do not have access to the therapeutic alternatives that CMS identifies for selected drugs. It would be unfair and arbitrary for CMS to evaluate Part D plan formulary submissions, including the identification of therapeutic alternatives contained in the submission, on a criteria that CMS never releases to the public. Formulary guidelines like the USP Medicare Model Guidelines provide a more predictable basis for administering a prescription drug benefit than nonpublic information. ..In short, while we urge CMS to align its methodology for selecting therapeutic alternatives as much as possible with Part D plans, we also request that CMS clarify that the therapeutic alternatives considered in the Medicare Drug Price Negotiation Program are distinct from the therapeutic alternatives that Part D plans must identify for purposes of formulary submissions and the overall administration of the prescription drug benefit. This will help ensure that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs. CMS can do this via an HPMS memo to Part D plans...III. Part D plans may continue to identify therapeutic alternatives in enrollee communications consistent with existing practices, regardless of CMS's identification of therapeutic alternatives for Medicare Drug Price Negotiation Program. ..Apart from formulary development, the issue of a drug's therapeutic alternatives also has implications on communications Part D sponsors are required to provide to enrollees. The Annual Notice of Change (ANOC) describes any changes to the plan's benefits, formularies, and costs for the upcoming year. The Evidence of Coverage (EOC) document describes the plan's benefits, coverage, and exclusions. Real-time benefit tools (RTBT) provide prescribers with information at the point-of-care on formulary and benefit information (including cost, formulary alternatives, and utilization management requirements). The monthly Explanation of Benefits (EOB) must include lower cost alternatives. ..While Part D plans are not required to include information about therapeutic alternatives in the ANOC or EOC, many voluntarily do so to help enrollees make informed decisions about their prescription drug coverage. This information is especially valuable for enrollees and prospective enrollees to fully understand the different treatment options available to them based on their unique circumstances. This transparency also promotes competition among Part D plans, as enrollees can better assess which plans are best for them. ..The RTBT and EOB rules have granted plans latitude in selecting which therapeutic alternatives would be displayed. CMS has stated that the "purpose of the beneficiary RTBT is to better inform beneficiaries about alternative medications," and thus, CMS allows "part D sponsors flexibility in implementing this requirement." For the EOB, CMS requires Part D sponsors to include lower-cost therapeutic alternatives but does not impose any specific requirements on plans on how they should identify those therapeutic alternatives...In summary, while Part D plans are required to communicate certain information to enrollees about therapeutic alternatives, CMS</p>
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provides plans with significant flexibility in the selection of those therapeutic alternatives. As such, CMS should explicitly clarify that the information on therapeutic alternatives that Part D plans choose to communicate to enrollees in required enrollee communications to beneficiaries and other regulatory requirements is not affected by CMS's selection of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program.

Hyperlink to
Table/Charts/Graphs -
Additional Materials for
Question 28
Evidence Submitted include
a cost-effectiveness
measure?

What type of Evidence is
shown?

Response to Question 29

Hyperlink to Citation -
Additional Materials for
Question 29

Question 29:
Comparative
Effectiveness
on Specific
Populations

Hyperlink to
Table/Charts/Graphs -
Additional Materials for
Question 29

Evidence Submitted include
a cost-effectiveness
measure?

What type of Evidence is
shown?

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Question	Sub-Question	Response
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	

Answers to Question #28 for Public Submission

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments regarding the therapeutic alternatives for Ustekinumab. Our members help administer the Part D prescription drug benefit on behalf of many Part D plan sponsors, and a central component of that function is the identification of therapeutic alternatives to develop comprehensive prescription drug formularies consistent with applicable statutory, regulatory, and clinical requirements, including ensuring formularies are not discriminatory.

In general, while we understand that CMS cannot disclose the specifics of their negotiations with manufacturers of selected drugs, we believe the public is best served by CMS disclosing as much about this process as possible, and otherwise aligning its methodology for selecting therapeutic alternatives with how Part D plans select therapeutic alternatives. Our comments focus on emphasizing the differences between identifying therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program, and the role that the identification of therapeutic alternatives plays under the Medicare Part D program's formulary standards and enrollee communication requirements. PCMA has three main points:

1. As a general principle, CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for the Part D program.
2. CMS should clarify in an HPMS memo to Part D plans that CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program will not impact the agency's existing approach towards evaluating Part D formulary design for compliance with Part D formulary requirements.
3. CMS should clarify in an HPMS memo that Part D plans retain discretion on how to communicate therapeutic alternatives to enrollees, and that CMS's identification of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program will not affect these enrollee communications.

We discuss these issues in more detail below.

I. CMS should identify therapeutic alternatives under the Medicare Drug Price Negotiation Program consistent with the guardrails that apply to Part D plan sponsors when identifying therapeutic alternatives for their formulary submissions.

Currently, Part D plan sponsors consider a variety of factors when identifying therapeutic alternatives for their formulary submissions, including but not limited to (i) clinical effectiveness, (ii) safety, (iii) price, (iv) availability, and (v) patient preferences. Importantly, these factors are considered within a regulatory framework that imposes certain overarching formulary requirements.

First, Part D plans must ensure that their formulary designs are nondiscriminatory.¹ CMS considers several criteria when assessing whether a formulary is nondiscriminatory. CMS may presumptively approve formulary designs which align with the United States Pharmacopoeia's (USP) Medicare Model Guidelines (MMGs) based on the view that the MMGs reflect a

¹ See 42 C.F.R. § 423.272(b)(2).

scientifically and-clinically-based taxonomy developed by an independent expert body without a vested financial interest in the Part D program. The MMGs are also important because they provide a guiding framework for Part D plans to use when determining therapeutic alternatives. The MMGs group drugs into categories and classes. These categories and classes generally encompass the universe of potential therapeutic alternatives for a given medical condition. This means that Part D plans can use the MMGs to identify the range of therapeutic alternatives to consider when developing their formularies.

Second, Part D plans must provide an adequate formulary, which among other things, means including at least two Part D drugs within a particular category or class of Part D drugs.² This minimum formulary standard helps ensure a wide range of treatment options for enrollees, even if they have complex or rare medical conditions. Additionally, this requirement promotes patient choice and competition among drug manufacturers because the ability for patients to access alternative treatments incentivizes drug manufacturers to lower prices and innovate. The requirement to include at least two drugs per category or class helps to ensure that patients with a given medical condition have at least two formulary treatment options available to them, even if there are few therapeutic alternatives. This requirement is important because it prevents Part D plans from excluding entire categories or classes of drugs from their formularies.

Third, Part D plans must consider cost sharing in the development of formularies. For example, CMS could raise concerns about formularies that place drugs on high cost-sharing tiers without placing therapeutic alternatives in preferable positions.³ CMS has also expressed concerns about "adverse tiering" where a plan sponsor assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high-cost medical condition to a high cost-sharing tier.⁴ In short, Part D plans must consider the enrollee's share of costs for a particular drug when considering therapeutic alternatives.

PCMA encourages CMS to identify therapeutic alternatives for the Medicare Drug Price Negotiation Program in the same way that Part D plans do for their formularies. This would ensure consistency in process across two closely related programs and avoid introducing multiple, confusing standards for the same underlying definitional term. At the very least, aligning the selection of therapeutic alternatives under the Medicare Drug Price Negotiation Program with Part D formulary submissions would give Part D plans some assurance that CMS's assessment of their formulary submissions will not be affected by CMS's own process of selecting therapeutic alternatives.

II. CMS's identification of therapeutic alternatives for the Medicare Drug Price Negotiation Program should not compromise the agency's evaluation of the adequacy of Part D plan formulary design, ensuring that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs.

PCMA acknowledges that CMS's identification of therapeutic alternatives under the Medicare Drug Price Negotiation Program is required by law and essential for successful drug pricing

² *Id.* at §

³ § 30.2.7, Chapter 6, Medicare Prescription Drug Manual ("The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.").

⁴ 87 Fed. Reg. 27208, 27303 (May 6, 2022).

negotiations. As stated above, we urge CMS to attempt to align its selection of therapeutic alternatives with how Part D plans select therapeutic alternatives.

That being said, it is important to recognize that the exercise of selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program and the Part D program, while overlapping in some areas, are ultimately distinct. Selecting therapeutic alternatives for the Medicare Drug Price Negotiation Program requires unique considerations that are not fully applicable to how Part D plans identify and leverage therapeutic alternatives for formulary development.⁵ Accordingly, we do not expect CMS to perfectly align itself with Part D plan sponsor methodologies for selecting therapeutic alternatives.

First, therapeutic alternatives are a statutory feature of the Medicare Drug Price Negotiation Program. CMS selects therapeutic alternatives when negotiating pricing for selected drugs because the statute *requires* the agency to do so. Even if the statute did not require CMS to identify therapeutic alternatives, CMS would likely need to do so because it supports the agency in carrying out its statutory mandate to negotiate a "maximum fair price" (MFP) with manufacturers. Importantly, the MFP applies in a vacuum without regards to affordability and relative competitiveness with other drugs that a beneficiary may access.

By contrast, while Part D plans are required to select therapeutic alternatives for formulary submissions, Part D plans select therapeutic alternatives based on a delicate balance between clinical comparability, cost-effectiveness, and beneficiary access. Unlike CMS, which is required to focus on a single drug in isolation when assessing therapeutic alternatives, Part D plans, PBMs, and their pharmacy and therapeutics (P&T) committees are tasked with developing comprehensive formularies that holistically meet the complex needs of their enrollees. Part D plans must, already, cover selected drugs on their formularies under the statute,⁶ and CMS's interpretation worryingly suggests that such coverage may also involve a preferred status designation.⁷ Additional indirect restrictions on formulary design stemming from CMS's evaluation criteria under the Medicare Drug Price Negotiation Program could significantly hamper Part D plans' ability to offer competitive plan designs. In light of the comprehensive considerations that Part D plans must consider in developing formularies, CMS must ensure plans retain flexibility to adequately weigh all of these factors when developing formularies, including identifying therapeutic alternatives.

Second, CMS's selection of therapeutic alternatives is a one-time event, done solely to determine the MFP for a selected drug. Once the MFP is determined, the drug's therapeutic alternatives play no further role in how Medicare beneficiaries access the selected drug.

In contrast, a Part D plan sponsor's selection of therapeutic alternatives is used in multiple ways, including formulary design, coverage determination, tiering exceptions, and Part D appeals. This means that Part D plans must carefully consider all potential scenarios in which their selection of therapeutic alternatives may be challenged.

Third, CMS's identification of therapeutic alternatives for purposes of the Drug Price Negotiation Program is nonpublic. CMS indicates in the Revised Guidance for the Medicare Drug Price

⁵ See 42 C.F.R. § 423.128(d)(4)(ii).

⁶ Social Security Act § 1860D-4(b)(3)(I).

⁷ See § 110, Medicare Drug Price Negotiation Program: Revised Guidance (June 30, 2023), <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>.

Negotiation Program that the agency will not unilaterally disclose any information pertaining to its negotiations with manufacturers, including the therapeutic alternatives identified for such negotiations. As a result, Part D plans do not have access to the therapeutic alternatives that CMS identifies for selected drugs. It would be unfair and arbitrary for CMS to evaluate Part D plan formulary submissions, including the identification of therapeutic alternatives contained in the submission, on a criteria that CMS never releases to the public. Formulary guidelines like the USP Medicare Model Guidelines provide a more predictable basis for administering a prescription drug benefit than nonpublic information.

In short, while we urge CMS to align its methodology for selecting therapeutic alternatives as much as possible with Part D plans, we also request that CMS clarify that the therapeutic alternatives considered in the Medicare Drug Price Negotiation Program are distinct from the therapeutic alternatives that Part D plans must identify for purposes of formulary submissions and the overall administration of the prescription drug benefit. This will help ensure that Medicare beneficiaries continue to have access to a broad range of affordable prescription drugs. CMS can do this via an HPMS memo to Part D plans.

III. Part D plans may continue to identify therapeutic alternatives in enrollee communications consistent with existing practices, regardless of CMS's identification of therapeutic alternatives for Medicare Drug Price Negotiation Program.

Apart from formulary development, the issue of a drug's therapeutic alternatives also has implications on communications Part D sponsors are required to provide to enrollees. The Annual Notice of Change (ANOC) describes any changes to the plan's benefits, formularies, and costs for the upcoming year. The Evidence of Coverage (EOC) document describes the plan's benefits, coverage, and exclusions. Real-time benefit tools (RTBT) provide prescribers with information at the point-of-care on formulary and benefit information (including cost, formulary alternatives, and utilization management requirements).⁸ The monthly Explanation of Benefits (EOB) must include lower cost alternatives.⁹

While Part D plans are not required to include information about therapeutic alternatives in the ANOC or EOC, many voluntarily do so to help enrollees make informed decisions about their prescription drug coverage. This information is especially valuable for enrollees and prospective enrollees to fully understand the different treatment options available to them based on their unique circumstances. This transparency also promotes competition among Part D plans, as enrollees can better assess which plans are best for them.

The RTBT and EOB rules have granted plans latitude in selecting which therapeutic alternatives would be displayed. CMS has stated that the "purpose of the beneficiary RTBT is to better inform beneficiaries about alternative medications," and thus, CMS allows "part D sponsors flexibility in implementing this requirement."¹⁰ For the EOB, CMS requires Part D sponsors to include lower-cost therapeutic alternatives but does not impose any specific requirements on plans on how they should identify those therapeutic alternatives.

⁸ § 119, Title I, Division CC, Consolidated Appropriations Act, 2021, Pub. L. No. 117-328 (amending section 1860D-4); *see also* 86 Fed. Reg. 5864, 5868 (Jan. 19, 2021).

⁹ 42 C.F.R. 423.138(e)(5).

¹⁰ 86 Fed. Reg. 5864, (May 6, 2022).

In summary, while Part D plans are required to communicate certain information to enrollees about therapeutic alternatives, CMS provides plans with significant flexibility in the selection of those therapeutic alternatives. As such, CMS should explicitly clarify that the information on therapeutic alternatives that Part D plans choose to communicate to enrollees in required enrollee communications to beneficiaries and other regulatory requirements is not affected by CMS's selection of therapeutic alternatives for purposes of the Medicare Drug Price Negotiation Program.

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Question	Sub-Question	Response
Question 26: Respondent Information	Selected Drug	USTEKINUMAB
	Q26 - Respondent Name	
	Q26 - Organization Name (if applicable)	Rheumatology Nurses Society (RNS)
	Respondent Email	
	Who is completing this form?	OTH
Question 27: Prescribing Information	Prescribing Information	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 28	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
	Response to Question 29	

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Question	Sub-Question	Response
Question 29: Comparative Effectiveness on Specific Populations	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	

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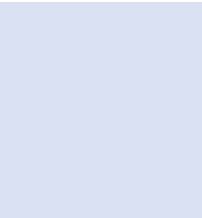
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Question	Sub-Question	Response
Question 31: Patient and Caregiver Experience	Response to Question 31	<p>The Rheumatology Nurses Society (RNS) is a professional organization committed to the development and education of nurses and other advanced practice providers (APPs) to benefit patients, family and community. The RNS officially formed in January 2007 as a not-for-profit professional organization. We are dedicated to healthcare professionals who are passionate about and committed to rheumatology and the promotion of excellence in the delivery of patient care. We work to remain the gold standard of rheumatology nursing practice through nurse certification, the creation of rheumatology nursing standards and protocols, and by acting as a primary resource to healthcare professionals and the patients they serve...We thank the agency for the opportunity to provide input on the ten medications selected to receive maximum fair prices (MFPs) beginning in 2026. We will limit our comments to Stelara® (ustekinumab), which is used to treat psoriasis and psoriatic arthritis, as well as several GI conditions. ..Among the ten selected drugs, ustekinumab is in a unique position because it has both a provider-administered formulation and a self-administered formulation: thus, this medication may be covered via Part B or Part D. By statute, drugs that are “not usually self-administered by the patient” are covered via Part B. As a result, for drugs that have both self- and provider-administered options, determining the meaning of the phrase “not usually self-administered” becomes critical. Under its current approach, CMS has set a blunt threshold, which is to determine whether more than 50% of beneficiaries who use the drug use the self-administered version. When that is the case, the Medicare Administrative Contractors (MACs) can exclude the medication from Part B coverage by adding it to the Self-Administered Drug Exclusion List (“SAD List”). That means that it can only be covered through Part D. ..The problems with the MACs' processes around the SAD List are longstanding and well-documented. For that reason, in the CY 2024 Medicare Physician Fee Schedule proposed rule, CMS issued a request for information related to coverage of drugs in this situation. ..In many ways, Stelara® (ustekinumab) has been the “poster child” for problems with the SAD List. In part, this issue is exacerbated by the fact that it has indications affecting very different patient populations. For rheumatology patients, joint damage may make it physically impossible to self-administer. Yet the current system does not include a formalized, easily accessible, and prompt way for such beneficiaries to seek an exemption after their medication is moved to the SAD List. That leaves beneficiaries who need provider administration without any way to access their medication. ..At this time, it is unclear how ustekinumab being subject to a maximum fair price (MFP) will affect this existing issue. On the one hand, beneficiary cost-sharing in Part D would be assessed against the MFP, which could help alleviate the financial barriers resulting from a drug being moved out of Part B, where most beneficiaries have supplemental coverage. On the other hand, when a dual-formulation drug gets an MFP in Part D, that may encourage the existing misbehavior by the MACs related to denying coverage in Part B, even for patients who</p>
Question 32: Executive Summary	Response to Question 32	



Question	Sub-Question
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	<p>Response</p> <p>have physical disabilities that prevent self-administration. ..For now, on behalf of our rheumatology patients, we wanted to ensure that CMS keeps this dynamic in mind as the agency moves forward with implementation of the Medicare Drug Price Negotiation Program. We urge CMS to ensure that medications with both provider-administered and self-administered options remain fully accessible to patients under a comprehensive regulatory paradigm, taking into account all interactions and potential unintended consequences between the MFPs and the SAD List for these unique medications.</p>
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Question	Sub-Question	Response
		<p>reasons, mostly because it stands to accelerate biosimilar adoption in the U.S. and help drive down system and patient costs. Such an outcome is wholly consistent with the statutory framework Congress created in the Biologics Price Competition and Innovation Act of 2009 (P.L. 111-148). However, CMS' implementation of the Act tends to do damage not only to this structure, but the future viability of the biosimilars industry. FDA's interchangeability decision on Stelara underscores that the potential success of this market hinges on CMS' setting of MFP for the innovative molecule. With four biosimilars to Stelara® projecting to launch within the next seven months, all of which may be deemed to be interchangeable upon FDA approval, the U.S. healthcare system is on the cusp of realizing the promise of the BPCIA: broad adoption of cost-competitive products that are highly similar to the innovative molecule, driving new savings for the U.S. healthcare system that create headroom for the development of new therapies and cures, while also protecting the solvency of Medicare and lowering out-of-pocket costs for Medicare beneficiaries. This market-based outcome has the potential to dwarf the savings that may be realized from IRA's negotiation framework alone.</p>
	<p>Evidence Submitted include a cost-effectiveness measure?</p> <p>What type of Evidence is shown?</p>	<p>Y</p> <p>N</p>
Question 28: Therapeutic Impact and Comparative Effectiveness	Therapeutic Impact and Comparative Effectiveness	<p>AVT04 is a ustekinumab monoclonal antibody that acts as inhibitors for interleukin (IL)-12 and IL-23. It is intended to be biosimilar to the reference product Stelara®. AVT04 would be indicated for the same indications as the innovator: treatment of patients with psoriatic arthritis, plaque psoriasis, and inflammatory bowel disease, which is an umbrella term for ulcerative colitis and Crohn disease...Section 351(i) of the Public Health Service Act ("PHS Act") defines biosimilarity to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." Therefore, consistent with the statute, AVT04 will have a highly similar profile to Stelara® and show no clinically meaningful difference in its use with patients. By creating an additional barrier for automatic substitution at the pharmacy counter, Congress created an additional barrier to wide adoption of biosimilars akin to what the U.S. healthcare system sees with small molecule generics. Indeed, to meet the standard for interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be substituted for the reference product without the intervention of the prescribing health care provider (see section 351(i)(3) of the PHS Act).</p>



Question	Sub-Question	Response
		<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED] FDA's guidance is a welcome development for many reasons, mostly because it stands to accelerate biosimilar adoption in the U.S. and help drive down system and patient costs. Such an outcome is wholly consistent with the statutory framework Congress created in the Biologics Price Competition and Innovation Act of 2009 (P.L. 111-148). However, CMS' implementation of the Act tends to do damage not only to this structure, but the future viability of the biosimilars industry. FDA's interchangeability decision on Stelara underscores that the potential success of this market hinges on CMS' setting of MFP for the innovative molecule. With four biosimilars to Stelara® projecting to launch within the next seven months, all of which may be deemed to be interchangeable upon FDA approval, the U.S. healthcare system is on the cusp of realizing the promise of the BPCIA: broad adoption of cost-competitive products that are highly similar to the innovative molecule, driving new savings for the U.S. healthcare system that create headroom for the development of new therapies and cures, while also protecting the solvency of Medicare and lowering out-of-pocket costs for Medicare beneficiaries. This market-based outcome has the potential to dwarf the savings that may be realized from IRA's negotiation framework alone. ..Under Section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar may submit a request, prior to the selected drug publication date, for CMS' consideration, to delay the inclusion of a negotiation-eligible drug that includes the reference product for the biosimilar. In guidance, CMS provided details on the implementation of the biosimilars special rule for initial price applicability year 2026. In order to be considered, delay requests had to be submitted by May 10, 2023, demonstrate a biosimilar application has been accepted for review or approved by the FDA, and show that clear and convincing evidence exists that the biosimilar will be marketed before September 1, 2025 (the date that is two years after the selected drug publication date for the initial price applicability year). To demonstrate clear and convincing evidence, CMS required, among other things, that biosimilar developers be clear of any intellectual property (IP) that would otherwise prohibit the marketing of their product. CMS noted in its guidance that it would deny requests if the biosimilar manufacturer was engaged in active litigation with the reference drug's manufacturer. At the time of CMS' arbitrary May 10, 2023 deadline, Alvotech was in active litigation with Johnson & Johnson and therefore could not satisfy CMS' requirements to grant the delay. Indeed, it seems all other biosimilar candidates for Stelara® could not satisfy CMS' arbitrary guidance as CMS noted “zero drugs would have been selected drugs for initial price applicability year 2026, absent the Biosimilar Delay.” ..However, on June 12, 2023 Alvotech and Teva announced they had reached a settlement and license agreement with Johnson & Johnson concerning AVT04 in the United States. The settlement grants a licensed entry date for AVT04 no later than February 21, 2025. Since CMS' May 10 deadline to submit a request for delay, additional manufacturers have announced settled entry dates that may create a robust competitive</p>

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Question Sub-Question

Response

marketplace for this molecule: Amgen on January 1, 2025; Celltrion on March 7, 2025; and Fresenius-Kabi on April 15, 2025. Therefore, pending FDA approval, Alvotech and Teva will be permitted to commercialize AVT04 in the United States along with two other manufacturers prior to the statute's March 31, 2025 deadline that prevents the assignation of a MFP and before September 1, 2025. By not exempting Stelara® from negotiation, CMS runs the risk of depriving Medicare and Medicare beneficiaries of additional savings beyond what negotiation alone can achieve. This dynamic is informed by the U.S. markets' experience with the launch of biosimilars to Humira® and certain insulin products. Indeed, recent data from these emerging competitive markets demonstrates that biosimilar developers are offering discounts off of WAC of 86%. The competitive market for Humira® and insulin markets are driving saving to all Americans, not just those in Medicare, and at a substantially more impactful rate. CMS runs the risk of stifling these competitive pressures in the Stelara® market by publishing the MFP before the market has the ability to form, or in the alternative if CMS persists in application of its arbitrary deadlines for plan year 2026, sets the MFP too low. Unlike Humira®, Stelara® does not have significant Medicare utilization. Teva estimates that approximately 14% of Stelara's® gross sales in the U.S. are through Medicare Part D. If CMS sets MFP on this molecule too low, the case for biosimilar entry will be challenged in Medicare Part D and commercial markets. ..By setting MFP for an innovator so close to biosimilar launch, there is a risk of creating a recurring monopoly for the innovator, while destroying current and future markets for biosimilars. While biosimilars are likely to be able to at least match the MFP set for innovators, with a lower innovator price it is more difficult for biosimilar manufacturers to use lower pricing to move market volume away from the innovator. This would force a future dynamic where the best-case scenario for biosimilars is to be only covered by PBMs at parity with the innovator. In this situation, there is limited incentive for a provider to prescribe or for a patient to use a biosimilar. This is evident in the real-life example of the Humira® biosimilar market. While multiple biosimilars have come to market in 2023, the innovator molecule has secured vast parity coverage (in 2023) by offering more rebates for payers. Nonetheless, Humira® biosimilars have been successful in lowering costs for the healthcare system but have not gained any notable market share. Biosimilars are not expected to gain share until payers begin to disadvantage Humira® in 2024 or 2025. In the Stelara® market, by setting a low MFP for the innovator, CMS risks replicating the same Humira® biosimilar marketplace dynamic, but in perpetuity. The lack of opportunity for biosimilars in this scenario will likely disincentive manufacture investment for future biosimilars. Without future biosimilar launches and investment, patients will not benefit from competitive pricing, and the innovators are likely to respond by retaining competitive monopolies with inflated pricing from commercial payers.

Hyperlink to
Table/Charts/Graphs -
Additional Materials for
Question 28

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Question

Sub-Question

Response

Evidence Submitted include a cost-effectiveness measure?

Y

What type of Evidence is shown?

N

Question 29: Comparative Effectiveness on Specific Populations

Response to Question 29

AVT04 is a ustekinumab monoclonal antibody that acts as inhibitors for interleukin (IL)-12 and IL-23. It is intended to be biosimilar to the reference product Stelara®. AVT04 would be indicated for the same indications as the innovator: treatment of patients with psoriatic arthritis, plaque psoriasis, and inflammatory bowel disease, which is an umbrella term for ulcerative colitis and Crohn disease...Section 351(i) of the Public Health Service Act ("PHS Act") defines biosimilarity to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." Therefore, consistent with the statute, AVT04 will have a highly similar profile to Stelara® and show no clinically meaningful difference in its use with patients. By creating an additional barrier for automatic substitution at the pharmacy counter, Congress created an additional barrier to wide adoption of biosimilars akin to what the U.S. healthcare system sees with small molecule generics. Indeed, to meet the standard for interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be substituted for the reference product without the intervention of the prescribing health care provider (see section 351(i)(3) of the PHS Act).

FDA's guidance is a welcome development for many reasons, mostly because it stands to accelerate biosimilar adoption in the U.S. and help drive down system and patient costs. Such an outcome is wholly consistent with the statutory framework Congress created in the Biologics Price Competition and Innovation Act of 2009 (P.L. 111-148). However, CMS' implementation of the Act tends to do damage not only to this structure, but the future viability of the biosimilars industry. FDA's

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Question	Sub-Question	Response
		interchangeability decision on Stelara underscores that the potential success of this market hinges on CMS' setting of MFP for the innovative molecule. With four biosimilars to Stelara® projecting to launch within the next seven months, all of which may be deemed to be interchangeable upon FDA approval, the U.S. healthcare system is on the cusp of realizing the promise of the BPCIA: broad adoption of cost-competitive products that are highly similar to the innovative molecule, driving new savings for the U.S. healthcare system that create headroom for the development of new therapies and cures, while also protecting the solvency of Medicare and lowering out-of-pocket costs for Medicare beneficiaries. This market-based outcome has the potential to dwarf the savings that may be realized from IRA's negotiation framework alone.
	Hyperlink to Citation - Additional Materials for Question 29	
	Hyperlink to Table/Charts/Graphs - Additional Materials for Question 29	
	Evidence Submitted include a cost-effectiveness measure?	Y
	What type of Evidence is shown?	N
Question 30: Addressing Unmet Medical Needs	Response to Question 30	
	Hyperlink to Citation - Additional Materials for Question 30 Hyperlink to Table/Charts/Graphs - Additional Materials for Question 30	

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Question	Sub-Question	Response
	Evidence Submitted include a cost-effectiveness measure?	
	What type of Evidence is shown?	
Question 31: Patient and Caregiver Experience	Response to Question 31	
Question 32: Executive Summary	Response to Question 32	<p>This letter is pursuant to the Center for Medicare and Medicaid Services (CMS) recent request for information about selected drugs and evidence about alternative treatments. Pursuant to Section 1194(e)(2) of the Inflation Reduction Act of 2022 (P.L.117-169) (the “Act”), Teva Pharmaceuticals, Inc. (“Teva”) is pleased to submit information as a manufacturer that does not manufacture the selected drug or its therapeutic alternative(s), but is the U.S. commercial partner for Alvotech, the developer and manufacturer of AVT04, a monoclonal antibody and biosimilar candidate to Stelara® (ustekinumab)...Like Stelara®, AVT04 binds to two cytokines, IL-12 and IL-23, which are involved in inflammatory and immune responses. AVT04 is an investigational product awaiting approval by the U.S. Food and Drug Administration (FDA) but was recently granted marketing approval by the Japanese Ministry of Health, Labor and Welfare. AVT04 promises to bring much needed competition to the U.S. pharmaceutical market and lower the price of Stelara® better than the Act's negotiation framework can. Additionally, CMS' implementation of the law is inconsistent with the statute and threatens the success of this market as well as future biosimilar products. It is critically important that CMS approach negotiation with Johnson & Johnson judiciously, realizing that equities exist with follow-on developers like Alvotech, that if ignored, will only cost the U.S. healthcare system more due to lost savings from delayed or forgone biosimilar competition. Therefore, Teva requests that CMS maximize the Maximum Fair Price (MFP) of Stelara® to every extent possible in order to preserve the business case for launch of AVT04 and other Stelara® biosimilars. ..Like CMS, Teva is committed to the success of the biosimilars market. We look forward to working with you to ensure implementation of the Act's negotiation framework is done in a way that does not artificially diminish the case for market development and competition that will lower the overall cost of Stelara® to the system and patients. To that end I would like to request a meeting with you to discuss this dynamic in greater detail so we can assist CMS in making therapies more affordable for Medicare.</p>

