



Maximum Fair Price (MFP) Explanation for Stelara

Introduction

In August 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) into law. For the first time, the law provides Medicare with the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. On March 15, 2023, the Centers for Medicare & Medicaid Services (CMS) issued [initial guidance](#) for the Medicare Drug Price Negotiation Program (the “Negotiation Program”), including requests for public comment on key elements. On June 30, 2023, CMS issued [revised guidance](#) detailing the requirements and parameters of the Negotiation Program for the first cycle of negotiations.¹ CMS engaged in negotiations with participating manufacturers between October 1, 2023 and August 1, 2024. These negotiations resulted in agreements establishing prices (which the IRA refers to as “maximum fair prices” or “MFPs”) that will be effective beginning in 2026 (the first cycle of negotiations is referred to as negotiations for “initial price applicability year 2026” because any agreed-upon prices will be effective in 2026). CMS published the agreed-upon MFPs on August 15, 2024.

The MFP explanation for Stelara for the agreed-upon MFP that resulted from the negotiations for initial price applicability year 2026 with Janssen Biotech, Inc., the manufacturer of Stelara (the “Primary Manufacturer”), provides information about the negotiations for Stelara. This information includes CMS’ perspective on the data considered that had the greatest impact in CMS’ determination of offers and consideration of counteroffers during the negotiation process through which the parties reached agreement on an MFP.² In some respects, the Primary Manufacturer had a different perspective on the relevant data. The parties to the negotiation had productive exchanges during the negotiation meetings described below in which they discussed their respective views, and these exchanges resulted in the exchange of offer(s) and counteroffer(s) among the parties and, ultimately, an agreed-upon MFP for Stelara.

On the basis of the factors described below and the related considerations and evidence, CMS negotiated with the Primary Manufacturer in good faith and consistent with the requirements of the law on behalf of people with Medicare and the Medicare program. Throughout the negotiation process and in accordance with the IRA, CMS’ goal was to achieve agreement with the Primary Manufacturer on the lowest possible MFP for Stelara that would be consistent with the process defined in the IRA for these price negotiations. CMS believes that the agreed-upon MFP achieves this aim. The negotiation process

¹ The [Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026](#), is referred to throughout this document as the revised guidance.

² Section 1195(a)(2) of the Social Security Act (the “Act”) requires CMS to publish an explanation for the MFP with respect to the factors as applied under section 1194(e) for each selected drug. The MFP explanation is discussed in section 60.6.1 of the [revised guidance](#).

ended in both parties agreeing to an MFP of \$4,695.00 for Stelara by the conclusion of the negotiation period on August 1, 2024.³ The agreed-upon MFP is set to take effect on January 1, 2026.

The MFP explanation contains the following components:

- MFP Explanation Narrative for Stelara
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 - Manufacturer-Specific Data
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 - Therapeutic Alternatives
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- Redacted Data Submitted by the Primary Manufacturer and Other Interested Parties for Stelara

MFP Explanation Narrative for Stelara

Summary of the Negotiation Process

CMS followed the negotiation process laid out in the IRA and in the revised guidance. On August 29, 2023, CMS announced the 10 selected drugs for the first cycle of negotiations, which included Stelara. The Primary Manufacturers of the selected drugs signed agreements to participate in the Negotiation Program by the deadline in the IRA of October 1, 2023 and submitted information on the selected drugs by the deadline in the IRA of October 2, 2023.

CMS collected relevant data from numerous sources, such as written submissions from the Primary Manufacturers and other interested parties in response to an information collection request issued for the Negotiation Program (referred to as the “Negotiation Program information collection request” throughout this document), feedback from patient-focused listening sessions, meetings between CMS and the Primary Manufacturers to discuss the information submitted, and CMS’ literature review.⁴

Using the information collected, CMS then developed initial offers for the selected drugs, which were based on the factors outlined in the IRA for CMS’ determination of offers and which CMS developed in accordance with the process described in the revised guidance.⁵ As required by the IRA, CMS’ initial offers each included a concise justification on the range of evidence and other information within the negotiation factors that CMS found compelling during the development of the initial offer. The Primary Manufacturers each responded by declining CMS’ initial offer and providing a written counteroffer and justification for such offer, including considerations based on the negotiation factors.

³ The MFP is expressed as the price per 30-days equivalent supply. See section 60.1 of the [revised guidance](#) and the [Negotiated Prices for Initial Price Applicability Year 2026 Fact Sheet](#) for additional information.

⁴ 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.

⁵ Section 1194(e) of the Act requires CMS to consider certain data as the basis for all offers and counteroffers in the negotiation. These data, which are referred to in this document as the “negotiation factors,” are discussed in more detail later in this document. More information on the negotiation factors is also available in sections 50, 60.3 and 60.4 of the [revised guidance](#). CMS’ process for developing the initial offers is described in section 60.3 of the revised guidance.

CMS considered each counteroffer proposed by the Primary Manufacturers and declined each counteroffer. CMS and each Primary Manufacturer then held three negotiation meetings. These meetings included extensive discussion of the negotiation factors, including any new information consistent with the factors that may have become available about the selected drugs or therapeutic alternatives, CMS' initial offer and the Primary Manufacturer's written counteroffer, and, in some cases, additional proposals for an MFP.

Across the first cycle of negotiations for all ten selected drugs, more than 50 revised offers or counteroffers were proposed by CMS or a Primary Manufacturer, not including the ten initial offers CMS made and the ten written counteroffers provided by Primary Manufacturers. During the negotiation meetings, CMS revised its initial offer for each selected drug upwards at least once in response to the discussions with the Primary Manufacturer. While many of the details of the negotiations are confidential between CMS and each Primary Manufacturer, the frequency of revised offers and counteroffers in the first cycle of negotiations indicates the robustness of the negotiations that occurred for each of the ten drugs. CMS' approach to its negotiations with each Primary Manufacturer turned on the particular details relevant to each selected drug and was sensitive to the issues raised during the course of CMS' conversations with the Primary Manufacturer. CMS anticipates this drug-specific approach will continue to inform CMS' negotiations with participating manufacturers in future cycles of negotiation.

Overall, in six of ten negotiations CMS moved more than the Primary Manufacturer during the meetings and for the final offer (if applicable) prior to reaching agreement, and in four of ten negotiations the Primary Manufacturer moved more than CMS prior to reaching agreement. For five of the selected drugs, this process of exchanging revised offers and counteroffers resulted in CMS and the Primary Manufacturer reaching an agreement on a negotiated price for the selected drug in association with a negotiation meeting. In four of these cases, CMS accepted a revised counteroffer proposed by the Primary Manufacturer. For the remaining five selected drugs, CMS sent a written final offer to the Primary Manufacturer, consistent with the process described in the revised guidance, and in each instance, the Primary Manufacturer accepted CMS' offer on or before the statutory deadline. Throughout the negotiation process, CMS and the Primary Manufacturers exchanged perspectives about a range of topics related to the negotiation factors, and while the parties did not always agree, CMS appreciated the Primary Manufacturers' engagement.

A detailed timeline of the negotiation process for Stelara is below.

- August 29, 2023: CMS announced the 10 selected drugs for initial price applicability year 2026
- October 1, 2023: Deadline for the Primary Manufacturer to sign an agreement to participate in the Negotiation Program
- October 2, 2023: Deadline for the Primary Manufacturer and the public to submit information related to Stelara in response to the Negotiation Program information collection request
- October 24, 2023: CMS met with the Primary Manufacturer regarding its response to the Negotiation Program information collection request
- November 14, 2023: CMS held a patient-focused listening session for Stelara
- February 1, 2024: CMS provided the Primary Manufacturer with CMS' initial offer
- March 1, 2024: The Primary Manufacturer rejected CMS' initial offer and provided CMS with a counteroffer
- March 29, 2024: CMS rejected the Primary Manufacturer's counteroffer and invited the Primary Manufacturer to a negotiation meeting
- April 30, 2024: CMS and the Primary Manufacturer met for the first negotiation meeting

- June 4, 2024: CMS and the Primary Manufacturer met for the second negotiation meeting
- June 25, 2024: CMS and the Primary Manufacturer met for the third negotiation meeting
- August 1, 2024: The negotiation period ended
- August 15, 2024: MFP of \$4,695.00 was published

Indications for Stelara

Stelara is a biologic that works by inhibiting proteins called interleukin (IL)-12 and IL-23 involved in the immune response pathways. Elevated concentrations of these proteins can be found in several inflammatory conditions, such as in patients with plaque psoriasis, psoriatic arthritis, Crohn’s disease, and ulcerative colitis.⁶

For Stelara, CMS included the following indications in its assessment⁷:

Description of indication	Terminology used in this document
Patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	Plaque psoriasis
Patients 6 years or older with active psoriatic arthritis	Psoriatic arthritis
Adult patients with moderately to severely active Crohn’s disease	Crohn’s disease
Adult patients with moderately to severely active ulcerative colitis	Ulcerative colitis

Table 1. For purposes of CMS’ consideration of indications for Stelara, CMS grouped certain indications using the terminology as shown in this table. CMS’ use of the terms listed here does not alter the FDA-approved indications for Stelara.

Factors Applied

Consistent with the IRA, CMS considered certain negotiation factors as the basis for determining all offers and counteroffers during the negotiation process.

The following negotiation factors are referred to in this document as “manufacturer-specific data”⁸:

- Research and development (R&D) costs of the Primary Manufacturer for Stelara and the extent to which the Primary Manufacturer has recouped R&D costs;
- Current unit costs of production and distribution of Stelara;

⁶ To compose this brief description, CMS used various sources, including MedlinePlus, a free online health information resource for patients and the general public. MedlinePlus is a service of the National Library of Medicine (NLM), a part of the U.S. National Institutes of Health (NIH). For more information about any drugs or conditions mentioned in this document, MedlinePlus can be accessed at: <https://medlineplus.gov/>.

⁷ CMS’ process for identifying indications for a selected drug was to identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act, using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. CMS considered off-label use when identifying indications if such use was included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia. CMS included indications that met these criteria during the negotiation period. Indications newly approved by FDA or included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia after the end of the negotiation period were not included.

⁸ These factors are listed at section 1194(e)(1) of the Act.

- Prior Federal financial support for novel therapeutic discovery and development with respect to Stelara;
- Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals for New Drug Applications and Biologics License Applications for Stelara;⁹ and
- Market data and revenue and sales volume data for Stelara in the United States (U.S.).

The following negotiation factors are referred to in this document as “evidence about Stelara and therapeutic alternatives to Stelara”¹⁰:

- The extent to which Stelara represents a therapeutic advance as compared to its existing therapeutic alternatives and the costs of such existing therapeutic alternatives;
- Prescribing information approved by the FDA for Stelara and therapeutic alternatives to Stelara;
- Comparative effectiveness of Stelara and therapeutic alternatives to Stelara, taking into consideration the effects of Stelara and therapeutic alternatives to Stelara on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations; and
- The extent to which Stelara and therapeutic alternatives to Stelara address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

The below sections describe how CMS considered and applied these factors during the negotiation process. CMS considered these factors, taking into account all data in totality during the negotiation process.

CMS and the Primary Manufacturer did not always agree on the information presented below, and the Primary Manufacturer was not restricted to consideration of these factors during the negotiation process but was free to discuss any topics with CMS it deemed relevant to its consideration of offer(s) and counteroffer(s) for Stelara.

Manufacturer-Specific Data

CMS considered the information submitted by the Primary Manufacturer related to the manufacturer-specific data factors. These factors include R&D costs and the extent to which the Primary Manufacturer has recouped R&D costs, current unit costs of production and distribution, prior Federal financial support, data on pending and approved patents and exclusivities recognized by the FDA, and market data, including revenue and sales volume data for the drug in the United States. CMS considered these factors in totality, as part of its application of the negotiation factors during the negotiation process.

⁹ New Drug Applications are approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and Biologics License Applications are approved under section 351(a) of the Public Health Service Act.

¹⁰ These factors are listed at section 1194(e)(2) of the Act. In accordance with section 1194(e)(2) and section 1182(e) of Title XI of the Act, CMS did not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and, consistent with section 1182(e) of Title XI of the Act, did not use quality adjusted life years (QALYs).

The Primary Manufacturer provided CMS with information for each of these factors in response to the Negotiation Program information collection request.¹¹ For R&D costs, CMS requested information separated into various categories of costs related to R&D, including acquisition costs, pre-clinical research costs, post-Investigational New Drug costs, costs of failed or abandoned products related to Stelara, and other allowable direct costs. CMS also requested the global and U.S. total lifetime net revenue for Stelara to provide insight into the extent to which the Primary Manufacturer has recouped R&D costs. CMS requested current average unit costs of production for Stelara and current average unit costs of distribution for Stelara separately, as well as a description of the methodology the Primary Manufacturer used to estimate such costs. For information related to prior Federal financial support, CMS requested the total amount of Federal financial support received, as well as a breakdown by various types of financial support, like tax credits and National Institutes of Health funding. CMS requested information on patents, both expired and unexpired, issued by the U.S. Patent and Trademark Office, patent applications, regulatory exclusivity periods, and active and pending FDA applications and approvals. For market data, CMS requested information about the prices for Stelara and volume dispensed for other payers in the U.S. market, including commercial payers (e.g., the U.S. commercial average net price), Medicaid (Medicaid Best Price), and other Federal payers (the Federal supply schedule price and the Big Four price).

Throughout the negotiation process, CMS holistically considered the information submitted by the Primary Manufacturer related to the manufacturer-specific data negotiation factors for the purpose of negotiating an MFP for Stelara. For example, CMS applied information on prices for Stelara available to other payers in the U.S. market and how they compared to any offers or counteroffers when considering whether a potential price was consistent with CMS' aim to arrive at an agreement on the lowest possible MFP. The totality of CMS' application of these factors, in conjunction with application of the factors described below, informed CMS' negotiation of the MFP with the Primary Manufacturer.

Evidence about Stelara and Therapeutic Alternatives to Stelara

CMS considered information related to the negotiation factors regarding evidence about Stelara and therapeutic alternatives to Stelara. CMS' holistic consideration of clinical benefit included evidence from sources such as: pivotal clinical trials, pre-specified subgroup analyses, clinical practice guidelines, expert consensus statements, comparative clinical evidence, published literature reviews, real-world evidence, and FDA prescription drug labeling, among others. CMS evaluated the evidence based on a variety of considerations, including relevance and credibility, giving priority to well-designed and well-conducted studies, as stated in the revised guidance.¹² In general, CMS prioritized direct comparative evidence (e.g., head-to-head randomized controlled trials) when available. CMS also reviewed mixed and/or

¹¹ In accordance with the revised guidance, CMS treats R&D costs and the extent to which they are recouped, unit costs of production and distribution, pending patent applications, and market, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available. For more information, see section 40.2.1 of the [revised guidance](#).

¹² In section 50.2 of the [revised guidance](#), CMS stated, "When reviewing the literature from the public and manufacturer submissions as well as literature from CMS' review, CMS will consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. CMS will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., has sufficient sample size) to answer the primary question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses."

indirect treatment comparisons (e.g., network meta-analyses) when available and real-world evidence (e.g., observational studies) when available as part of its holistic assessment of comparative evidence.

In addition to information from the Primary Manufacturer, CMS received information from the public, including from patients during the patient-focused listening session held by CMS on November 14, 2023.¹³ Patient input was important to CMS’ consideration of the evidence about Stelara and therapeutic alternatives to Stelara, including to help identify outcomes of interest for patients and to understand additional considerations such as patients’ preferences with regard to potential treatments for conditions treated by Stelara. For example, speakers at the patient-focused listening session shared perspectives that autoimmune conditions are nuanced, that what works well for one person may not work for another, and that treatments may also lose effectiveness over time. These were several considerations among the many that informed CMS’ understanding of the factors regarding evidence about Stelara and its therapeutic alternatives. Throughout all of the patient-focused listening sessions for the first cycle of negotiations, speakers provided insight on the importance of affordability and access, which provided CMS helpful context for the speakers’ described experiences.

Therapeutic Alternatives

The IRA directs CMS to compare Stelara to therapeutic alternatives in its determination of offers and consideration of counteroffers for Stelara.¹⁴ In the revised guidance, CMS defines a therapeutic alternative for the first cycle of negotiations as a pharmaceutical product that is clinically comparable to the selected drug.¹⁵

Importantly, use of the term “therapeutic alternative” in this MFP explanation is limited to the purposes and definition outlined in the IRA and the revised guidance. Use of this term does not suggest that CMS believes such drugs are interchangeable or otherwise universally appropriate to prescribe for an individual in place of Stelara or that these are the only pharmaceutical treatments that might be used by a person with one of the indications treated by Stelara. CMS trusts that patients and health care providers will continue to choose the therapy that best suits a given patient’s needs based on the patient’s health, history, experience, and preferences, the provider’s expertise, FDA-approved prescribing information, and relevant clinical guidelines, as applicable.

During the negotiation process, CMS identified therapeutic alternatives to Stelara based on a holistic consideration of the available evidence from a range of sources. In addition to the sources listed above, such as data submitted by the Primary Manufacturer and the public and widely accepted clinical guidelines, other examples of data sources used include the following: drug classification systems commonly used in the public and commercial sector for formulary development, indications included in CMS-approved Part D compendia, and drug or drug class reviews.

The following table lists the therapeutic alternatives, among all clinically comparable alternatives that CMS reviewed, which were particularly relevant to CMS’ consideration, due to guideline recommendations, utilization in the Medicare population, and other considerations.

Indication	Therapeutic Alternatives
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¹³ The redacted transcript for this patient-focused listening session is available at the following link: <https://www.cms.gov/files/document/stelara-transcript-111423.pdf>.

¹⁴ See section 1194(e)(2) of the Act and sections 50, 60.3 and 60.4 of the [revised guidance](#) for additional information.

¹⁵ This definition appears in Appendix C of the [revised guidance](#).

Plaque psoriasis	<ul style="list-style-type: none"> • Adalimumab • Etanercept • Guselkumab • Infliximab • Ixekizumab • Risankizumab • Secukinumab • Tildrakizumab
Psoriatic arthritis	<ul style="list-style-type: none"> • Adalimumab • Etanercept • Guselkumab • Infliximab • Ixekizumab • Risankizumab • Secukinumab
Crohn’s disease	<ul style="list-style-type: none"> • Adalimumab • Infliximab • Risankizumab • Vedolizumab
Ulcerative colitis	<ul style="list-style-type: none"> • Adalimumab • Infliximab • Vedolizumab

Table 2. Use of the term “therapeutic alternative” in this MFP explanation is limited to the purposes and definition outlined in the IRA and the revised guidance. Use of this term does not suggest that CMS believes such drugs are interchangeable or otherwise universally appropriate to prescribe for an individual in place of Stelara or that these are the only pharmaceutical treatments that might be used by a person with one of the indications treated by Stelara. CMS trusts that patients and health care providers will continue to choose the therapy that best suits a given patient’s needs based on the patient’s health, history, experience, and preferences, the provider’s expertise, FDA-approved prescribing information, and relevant clinical guidelines, as applicable.

CMS considered utilization for Stelara and its therapeutic alternatives by indication as one part of its application of the negotiation factors.

Outcomes and Additional Considerations

Outcomes are measurable effects or impacts of a treatment or intervention. Outcomes can be used to measure differences in the safety or effectiveness of different treatments. Patient-centered outcomes are outcomes identified by patients that are important to how they feel, function, or survive. To consider comparative effectiveness between Stelara and therapeutic alternatives to Stelara, CMS identified clinically relevant and patient-centered outcomes of interest from the body of available literature to evaluate for each indication of Stelara. CMS then identified evidence comparing Stelara to therapeutic alternatives based on these outcomes. The following table includes a non-exhaustive list of outcomes that were of interest to CMS in its consideration of Stelara:

Indication	Effectiveness Outcomes	Safety Outcomes
Plaque psoriasis	<ul style="list-style-type: none"> • Disease extent and severity (e.g., PASI 75) • HRQoL (e.g., DLQI) 	<ul style="list-style-type: none"> • Serious adverse events • Serious infection • Tolerability (e.g., discontinuation due to adverse events)
Psoriatic arthritis	<ul style="list-style-type: none"> • Disease signs and symptoms of psoriatic arthritis (e.g., ACR 20, PASI 75) • Structural damage (e.g., radiographic non-progression) • Physical function (e.g., HAQ-DI) • HRQoL (e.g., Psoriatic Arthritis QoL) 	<ul style="list-style-type: none"> • Serious adverse events • Serious infection • Tolerability (e.g., discontinuation due to adverse events)
Crohn’s disease	<ul style="list-style-type: none"> • Clinical remission (e.g., Crohn’s Disease Activity Index) • Steroid-free remission • Endoscopic remission (e.g., Simple Endoscopic Score for Crohn’s Disease) 	<ul style="list-style-type: none"> • Serious adverse events • Serious infection • Tolerability (e.g., discontinuation due to adverse events)
Ulcerative colitis	<ul style="list-style-type: none"> • Clinical remission (e.g., Mayo score) • Steroid-free remission • Endoscopic improvement (e.g., Mayo score) • HRQoL (e.g., Inflammatory Bowel Disease Questionnaire) 	<ul style="list-style-type: none"> • Serious adverse events • Serious infections • Tolerability (e.g., discontinuation due to adverse events)

Table 3. ACR = American College of Rheumatology; DLQI = Dermatology Life Quality Index Questionnaire; HAQ-DI = Health Assessment Questionnaire - Disability Index; HRQoL = health-related quality of life; PASI = Psoriasis Area and Severity Index; QoL = quality of life. Outcomes identified in this table were of interest to CMS in its evaluation of Stelara. Evidence to support an assessment may not have been available for every outcome of interest.

Outcomes, like those listed above, were identified as being of interest to CMS based on their importance to patients and their ability to measure how effective and safe a drug is when used to treat these indications. For example, for Crohn’s disease and ulcerative colitis, achieving and maintaining remission of symptoms and reducing need for steroids are key outcomes that are often used to evaluate the effectiveness of treatments. In addition, across indications, the risk of serious adverse events and tolerability, or the degree to which patients can tolerate adverse events associated with taking a drug, are outcomes that reflect important safety considerations for patients and their health care providers when evaluating drugs for these indications.

Additionally, CMS considered the extent to which Stelara represents a therapeutic advance as compared to existing therapeutic alternatives, and the extent to which Stelara and its therapeutic alternatives address an unmet medical need. CMS also evaluated access, equity, and health outcomes for specific populations (including individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations).

For the purpose of negotiating the MFP for Stelara, CMS holistically considered the negotiation factors regarding evidence about Stelara and therapeutic alternatives to Stelara, including consideration of the clinical benefit of Stelara in the context of its therapeutic alternatives. For example, CMS applied its understanding of the comparative effectiveness of Stelara and its therapeutic alternatives for each of the identified indications, as well as additional contextual considerations, when negotiating with the Primary Manufacturer. Examples of additional contextual considerations for Stelara and its therapeutic alternatives include the treatment complexity of these drugs (e.g., route of administration and frequency), use in co-occurring conditions (e.g., inflammatory bowel disease and psoriatic arthritis), and specific disease manifestations (e.g., scalp or nail involvement in patients with plaque psoriasis).

Throughout the negotiation process, including the development of the initial offer and in the consideration of any offers and counteroffers, CMS applied these and other factors regarding evidence about Stelara and therapeutic alternatives. The totality of CMS' application of these factors, in conjunction with application of the manufacturer-submitted data negotiation factors described above, informed CMS' negotiation of the MFP with the Primary Manufacturer.

Citations to Data Reviewed during the Negotiation Process for Stelara

CMS provides below a list of citations representative of evidence that CMS reviewed during the negotiation process, including citations provided by the Primary Manufacturer and the public in response to the Negotiation Program information collection request, those included in CMS' initial offer concise justification, and other citations which were considered during the evaluation of the Primary Manufacturer's counteroffer and during negotiation meetings.

Consistent with the IRA and section 1182(e) of Title XI of the Act, CMS did not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill, and, consistent with section 1182(e) of Title XI of the Act, did not use quality adjusted life years (QALYs). Inclusion on this list of a citation that contains such evidence does not mean that CMS used such evidence in the course of the negotiation.

This list is intended to provide insight into the range of evidence that various parties, including CMS and the Primary Manufacturer, identified as being relevant to the negotiation. This list does not represent the totality of evidence that CMS reviewed and considered as part of its holistic consideration of the negotiation factors in the determination of any offers and consideration of any counteroffers.

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5. AbbVie's SKYRIZI® (risankizumab) Versus STELARA® (ustekinumab) Head-to-Head Study in Crohn's Disease Meets All Primary and Secondary Endpoints [Internet] AbbVie Inc.; 2023 Oct 15. Available from: <https://news.abbvie.com/2023-10-15-AbbVies-SKYRIZI-R-risankizumab-Versus-STELARA-R-ustekinumab-Head-to-Head-Study-in-Crohns-Disease-Meets-All-Primary-and-Secondary-Endpoints>.
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9. Al-Janabi A, Jabbar-Lopez ZK, Griffiths CEM, Yiu ZZN. Risankizumab vs. ustekinumab for plaque psoriasis: a critical appraisal. *Br J Dermatol*. 2019;180(6):1348-51. Epub 20190327. doi: 10.1111/bjd.17624. PubMed PMID: 30632140.
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11. Amgen, Inc. Enbrel (etanercept) [package insert]. U.S. Food and Drug Administration. Revised Oct 2023. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf.
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Redacted Negotiation Meeting Summaries for Stelara

Below are summaries of the negotiation meetings between CMS and the Primary Manufacturer, which include redacted information regarding the negotiation meetings and exchange of offers and counteroffers in the meetings.



SUBJECT: Meeting Summary from Negotiation Meeting between the Centers for Medicare & Medicaid Services (CMS) and Janssen Biotech, Inc. regarding Stelara on April 30, 2024

Background: Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169), signed into law on August 16, 2022, established the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”) to enable the Centers for Medicare & Medicaid Services (CMS) to negotiate maximum fair prices (MFPs) with willing manufacturers for certain high expenditure, single source drugs and biological products. Janssen Biotech, Inc. (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Stelara (hereafter “the Selected Drug”).

In accordance with revised guidance and in the course of negotiation for the Selected Drug, CMS invited the Primary Manufacturer to a negotiation meeting when rejecting the Primary Manufacturer’s counteroffer, and the Primary Manufacturer accepted CMS’ invitation. CMS shared a proposed meeting agenda with the Primary Manufacturer approximately two weeks before the meeting. The Primary Manufacturer had the opportunity to request additions or edits to the agenda at least one week ahead of the meeting. This document includes a summary prepared by CMS of the first negotiation meeting, which was held on April 30, 2024, between 12:30PM ET and 3:00PM ET.

CMS Attendees:

1. Dan Heider, Director, Division of Rebate Agreements and Drug Price Negotiation
2. Min Kwon, Division of Rebate Agreements and Drug Price Negotiation
3. Tina Li, Medicare Drug Rebate and Negotiations Group
4. Corey Rosenberg, Deputy Director, Division of Rebate Agreements and Drug Price Negotiation
5. Lee Staley, Representative from the Office of the General Counsel
6. Lara Strawbridge, Deputy Director of Policy, Medicare Drug Rebate and Negotiations Group

Primary Manufacturer Attendees:

1. Lee Blevins, Senior Director, Strategic Account Managers for Emerging Government Policy
2. Andrew Greenspan, MD, Chief Global Medical Affairs Officer (virtual attendance)
3. Perry Knight, JD, MHA, Vice President, Law
4. Jacqueline Roche, DrPH, Head, Payment and Delivery Reform, Government Affairs and Policy
5. John Schaeffer, MBA, Senior Director, Strategy and Operations for Emerging Government Policy
6. Kimberly Woodruff, PharmD, PhD, Head, Real World Value and Evidence, Immunology

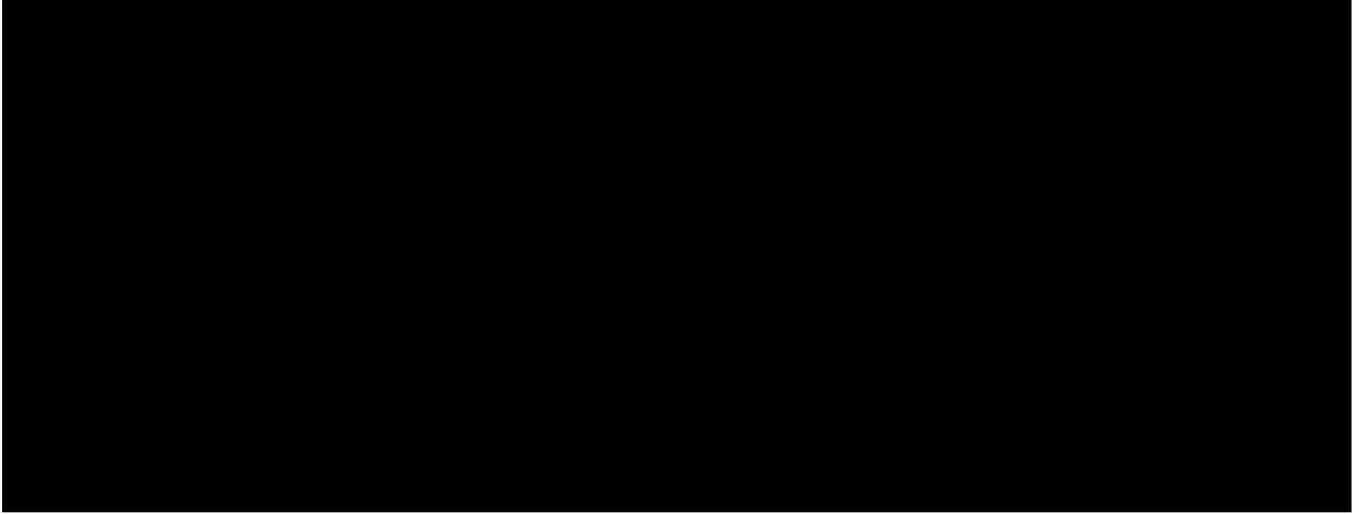
Topics: The discussion focused on topics outlined in the final agenda for the meeting, which was as follows:¹

- Introductions and meeting reminders
- CMS to walk through their procedural approach for developing an initial offer, including:
 - Process for evaluating the clinical value for each indication
 - Understanding of how CMS translated clinical rating Likert scales to initial price offer
 - Understanding of CMS methodology for incorporating 'additional factors' in establishing clinical benefit and an upward/downward adjustment
- Review of Janssen’s appropriate therapeutic alternatives for this exercise and other elements in rebuttal to CMS proposed initial price offer

¹ Note: This agenda may be inclusive of topics proposed by the Primary Manufacturer.

- CMS assessment of Janssen's counteroffer based on initial offer and procedural approach
- Next steps

Offers/Counteroffers Exchanged:





SUBJECT: Meeting Summary from Negotiation Meeting between the Centers for Medicare & Medicaid Services (CMS) and Janssen Biotech, Inc. regarding Stelara on June 4, 2024

Background: Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169), signed into law on August 16, 2022, established the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”) to enable the Centers for Medicare & Medicaid Services (CMS) to negotiate maximum fair prices (MFPs) with willing manufacturers for certain high expenditure, single source drugs and biological products. Janssen Biotech, Inc. (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Stelara (hereafter “the Selected Drug”).

In accordance with revised guidance and in the course of negotiation for the Selected Drug, because CMS and the Primary Manufacturer did not reach agreement on an MFP in the first negotiation meeting held on April 30, 2024, each party had the opportunity to request one additional negotiation meeting, resulting in a maximum of three meetings. CMS requested a second negotiation meeting, and the Primary Manufacturer accepted the invitation. CMS shared a proposed meeting agenda with the Primary Manufacturer approximately two weeks before the meeting. The Primary Manufacturer had the opportunity to request additions or edits to the agenda at least one week ahead of the meeting. This document includes a summary prepared by CMS of the second negotiation meeting, which was held on June 4, 2024 between 10:00 AM ET and 12:30 PM ET.

CMS Attendees:

1. Dan Heider, Director, Division of Rebate Agreements and Drug Price Negotiation
2. Min Kwon, Division of Rebate Agreements and Drug Price Negotiation
3. Tina Li, Medicare Drug Rebate and Negotiations Group
4. Corey Rosenberg, Deputy Director, Division of Rebate Agreements and Drug Price Negotiation
5. Lee Staley, Representative from the Office of the General Counsel
6. Lara Strawbridge, Deputy Director of Policy, Medicare Drug Rebate and Negotiations Group

Primary Manufacturer Attendees:

1. Lee Blevins, Senior Director, Strategic Account Managers for Emerging Government Policy
2. Andrew Greenspan, MD, Chief Global Medical Affairs Officer
3. Julia Kiechel, Senior Counsel (virtual attendance)
4. Jacqueline Roche, DrPH, Head, Payment and Delivery Reform, Government Affairs and Policy
5. John Schaeffer, MBA, Senior Director, Strategy and Operations for Emerging Government Policy
6. Kimberly Woodruff, PharmD, PhD, Head, Real World Value and Evidence, Immunology

Topics: The discussion focused on topics outlined in the final agenda for the meeting, which was as follows:¹

- Introductions and meeting reminders
- Any additional information from the Primary Manufacturer on comparative evidence for Stelara and CMS’ identified therapeutic alternatives (TNFi and non-TNFis), including among patients with Crohn's disease and ulcerative colitis
- Review why treatment persistence and drug survival are the same
- Discuss, for each indication, Primary Manufacturer’s rationale for upward adjustment in rating
- Review why STELARA® is differentiated from TNFi

¹ Note: This agenda may be inclusive of topics proposed by the Primary Manufacturer.

- Any other considerations that CMS and the Primary Manufacturer would like to discuss
- Next steps

Offers/Counteroffers Exchanged:





SUBJECT: Meeting Summary from Negotiation Meeting between the Centers for Medicare & Medicaid Services (CMS) and Janssen Biotech, Inc. regarding Stelara on June 25, 2024

Background: Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169), signed into law on August 16, 2022, established the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”) to enable the Centers for Medicare & Medicaid Services (CMS) to negotiate maximum fair prices (MFPs) with willing manufacturers for certain high expenditure, single source drugs and biological products. Janssen Biotech, Inc. (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Stelara (hereafter “the Selected Drug”).

In accordance with revised guidance and in the course of negotiation for the Selected Drug, because CMS and the Primary Manufacturer did not reach agreement on an MFP in the second negotiation meeting, which was requested by CMS and held on June 4, 2024, the Primary Manufacturer had the opportunity to request one additional negotiation meeting, resulting in a maximum of three meetings. The Primary Manufacturer requested a third negotiation meeting, and CMS accepted the invitation. CMS shared a proposed meeting agenda with the Primary Manufacturer approximately two weeks before the meeting. The Primary Manufacturer had the opportunity to request additions or edits to the agenda at least one week ahead of the meeting. This document includes a summary prepared by CMS of the third negotiation meeting, which was held on June 25, 2024 between 10:00 AM ET and 12:30 PM ET.

CMS Attendees:

1. Dan Heider, Director, Division of Rebate Agreements and Drug Price Negotiation
2. Min Kwon, Division of Rebate Agreements and Drug Price Negotiation
3. Tina Li, Medicare Drug Rebate and Negotiations Group
4. Corey Rosenberg, Deputy Director, Division of Rebate Agreements and Drug Price Negotiation
5. Lee Staley, Representative from Office of the General Counsel
6. Lara Strawbridge, Deputy Director of Policy, Medicare Drug Rebate and Negotiations Group

Primary Manufacturer Attendees:

1. Lee Blevins, Senior Director, Strategic Account Managers for Emerging Government Policy
2. Andrew Greenspan, MD, Chief Global Medical Affairs Officer (virtual attendance)
3. Perry Knight, JD, MHA, Vice President, Law
4. Shanthy Krishnarajah, MPH, MBA/MS, PhD, Senior Director, Scientific Evidence and Policy Research - New Products and IRA
5. Jacqueline Roche, DrPH, Head, Payment and Delivery Reform, Government Affairs and Policy
6. John Schaeffer, MBA, Senior Director, Strategy and Operations for Emerging Government Policy

Topics: The discussion focused on topics outlined in the final agenda for the meeting, which was as follows:¹

- Introductions and meeting reminders
- Revised offer/counteroffer price discussion
- Any other considerations that CMS or the Primary Manufacturer would like to discuss
- Next steps

¹ Note: This agenda may be inclusive of topics proposed by the Primary Manufacturer.

Offers/Counteroffers Exchanged:

