



# Maximum Fair Price (MFP) Explanation for Januvia

## 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.<sup>1</sup> 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 Januvia for the agreed-upon MFP that resulted from the negotiations for initial price applicability year 2026 with Merck Sharp Dohme, the manufacturer of Januvia (the “Primary Manufacturer”), provides information about the negotiations for Januvia. 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.<sup>2</sup> 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 Januvia.

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 Januvia 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

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<sup>1</sup> 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.

<sup>2</sup> 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 \$113.00 for Januvia by the conclusion of the negotiation period on August 1, 2024.<sup>3</sup> The agreed-upon MFP is set to take effect on January 1, 2026.

The MFP explanation contains the following components:

- MFP Explanation Narrative for Januvia
  - Summary of the Negotiation Process
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  - Evidence about Januvia and Therapeutic Alternatives to Januvia
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  - Citations to Data Reviewed during the Negotiation Process for Januvia
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- Redacted Data Submitted by the Primary Manufacturer and Other Interested Parties for Januvia

## MFP Explanation Narrative for Januvia

### 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 Januvia. 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.<sup>4</sup>

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.<sup>5</sup> 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.

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<sup>3</sup> 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.

<sup>4</sup> 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](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202306-0938-013).

<sup>5</sup> 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 Januvia 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 Januvia in response to the Negotiation Program information collection request
- October 26, 2023: CMS met with the Primary Manufacturer regarding its response to the Negotiation Program information collection request
- November 7, 2023: CMS held a patient-focused listening session for Januvia
- 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 22, 2024: CMS and the Primary Manufacturer met for the first negotiation meeting

- May 29, 2024: CMS and the Primary Manufacturer met for the second negotiation meeting
- June 26, 2024: CMS and the Primary Manufacturer met for the third negotiation meeting
- August 1, 2024: The negotiation period ended
- August 15, 2024: MFP of \$113.00 was published

## Indication for Januvia

Januvia is a dipeptidyl peptidase-4 inhibitor that works by increasing the amounts of certain hormones in the body that help lower the amount of sugar in the blood when it is too high. Januvia is used to treat type 2 diabetes mellitus (T2DM) in combination with diet and exercise.<sup>6</sup>

For Januvia, CMS included the following indication in its assessment: as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. CMS refers to this indication as “T2DM” in this document.<sup>7</sup> CMS’ use of this term does not alter the FDA-approved indication for Januvia.

## 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”<sup>8</sup>:

- Research and development (R&D) costs of the Primary Manufacturer for Januvia and the extent to which the Primary Manufacturer has recouped R&D costs;
- Current unit costs of production and distribution of Januvia;
- Prior Federal financial support for novel therapeutic discovery and development with respect to Januvia;
- 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 Januvia;<sup>9</sup> and
- Market data and revenue and sales volume data for Januvia in the United States (U.S.).

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<sup>6</sup> 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/>.

<sup>7</sup> 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.

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

<sup>9</sup> 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.

The following negotiation factors are referred to in this document as “evidence about Januvia and therapeutic alternatives to Januvia”<sup>10</sup>:

- The extent to which Januvia represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives;
- Prescribing information approved by the FDA for Januvia and therapeutic alternatives to Januvia;
- Comparative effectiveness of Januvia and therapeutic alternatives to Januvia, taking into consideration the effects of Januvia and therapeutic alternatives to Januvia on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations; and
- The extent to which Januvia and therapeutic alternatives to Januvia 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 Januvia.

## 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.

The Primary Manufacturer provided CMS with information for each of these factors in response to the Negotiation Program information collection request.<sup>11</sup> 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 Januvia, and other allowable direct costs. CMS also requested the global and U.S. total lifetime net revenue for Januvia 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 Januvia and current average unit

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<sup>10</sup> 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).

<sup>11</sup> 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](#).

costs of distribution for Januvia 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 Januvia 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 Januvia. For example, CMS applied information on prices for Januvia 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 Januvia and Therapeutic Alternatives to Januvia

CMS considered information related to the negotiation factors regarding evidence about Januvia and therapeutic alternatives to Januvia. 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.<sup>12</sup> In general, CMS prioritized direct comparative evidence (e.g., head-to-head randomized controlled trials) when available. CMS also reviewed mixed and/or 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 7, 2023.<sup>13</sup> Patient input was important to CMS' consideration of the evidence about Januvia and therapeutic alternatives to Januvia, including to help identify outcomes of interest for patients and to understand additional considerations such as the importance of managing T2DM and reducing the impact of its complications. For example, speakers at the patient-focused listening session shared that

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<sup>12</sup> 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."

<sup>13</sup> The redacted transcript for this patient-focused listening session is available at the following link: <https://www.cms.gov/files/document/januvia-transcript-110723.pdf>.

because Januvia can help control blood sugar, it in turn could prevent or delay worsening of diabetes-related complications, such as nerve damage. This was one consideration among the many that informed CMS’ understanding of the factors regarding evidence about Januvia 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 Januvia to therapeutic alternatives in its determination of offers and consideration of counteroffers for Januvia.<sup>14</sup> 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.<sup>15</sup>

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 Januvia or that these are the only pharmaceutical treatments that might be used by a person with the indication treated by Januvia. 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 Januvia 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
T2DM	<ul style="list-style-type: none"> <li>• Dapagliflozin</li> <li>• Dulaglutide</li> <li>• Empagliflozin</li> <li>• Glimepiride</li> <li>• Glipizide</li> <li>• Linagliptin</li> <li>• Metformin</li> <li>• Pioglitazone</li> <li>• Semaglutide</li> </ul>

*Table 1.* T2DM = type 2 diabetes mellitus. 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

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

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



drugs are interchangeable or otherwise universally appropriate to prescribe for an individual in place of Januvia or that these are the only pharmaceutical treatments that might be used by a person with the indication treated by Januvia. 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.

## 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 Januvia and therapeutic alternatives to Januvia, CMS identified clinically relevant and patient-centered outcomes of interest from the body of available literature to evaluate for the indication of Januvia. CMS then identified evidence comparing Januvia and to its 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 Januvia:

Indication	Effectiveness Outcomes	Safety Outcomes
T2DM	<ul style="list-style-type: none"> <li>Glycemic control (e.g., hemoglobin A1c)</li> </ul>	<ul style="list-style-type: none"> <li>Serious adverse events</li> <li>Tolerability (e.g., discontinuation due to adverse events)</li> <li>Hypoglycemia</li> </ul>

*Table 2.* T2DM = type 2 diabetes mellitus. Outcomes identified in this table were of interest to CMS in its evaluation of Januvia. 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 this indication. For example, glycemic control is an important outcome in the management of T2DM, as poor glycemic control is associated with increased risk of developing complications related to diabetes like kidney disease and nerve damage, among others. In addition, hypoglycemia, or low blood sugar, is an outcome reflecting an important safety consideration when evaluating drugs for this indication.

Additionally, CMS considered the extent to which Januvia represents a therapeutic advance as compared to existing therapeutic alternatives, and the extent to which Januvia 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 Januvia, CMS holistically considered the negotiation factors regarding evidence about Januvia and its therapeutic alternatives, including consideration of the clinical benefit of Januvia in the context of its therapeutic alternatives. For example, CMS applied its understanding of the comparative effectiveness of Januvia and its therapeutic alternatives, including the potential for side effects, like hypoglycemia, that can particularly affect the elderly population, when negotiating with the Primary Manufacturer. CMS' holistic assessment was informed by additional contextual considerations, such as use in patients with certain common co-occurring conditions (e.g., cardiovascular disease, heart failure, and chronic kidney disease), complexity of treatment regimens, FDA safety labeling, and patient preferences regarding treatment.



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 Januvia 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 Januvia

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.

1. Abbatecola AM, Maggi S, Paolisso G. New approaches to treating type 2 diabetes mellitus in the elderly: role of incretin therapies. *Drugs Aging*. 2008;25(11):913-25. doi: 10.2165/0002512-200825110-00002. PubMed PMID: 18947259.
2. Abdelhafiz AH, Koay L, Sinclair AJ. The effect of frailty should be considered in the management plan of older people with Type 2 diabetes. *Future Sci OA*. 2016;2(1):FSO102. Epub 20160212. doi: 10.4155/fsoa-2015-0016. PubMed PMID: 28031949; PubMed Central PMCID: PMC5137864.
3. Abdelhafiz AH, Rodriguez-Manas L, Morley JE, Sinclair AJ. Hypoglycemia in older people - a less well recognized risk factor for frailty. *Aging Dis*. 2015;6(2):156-67. Epub 20150310. doi: 10.14336/AD.2014.0330. PubMed PMID: 25821643; PubMed Central PMCID: PMC4365959.
4. Ahren B, Masmiquel L, Kumar H, Sargin M, Karsbol JD, Jacobsen SH, et al. Efficacy and safety of once-weekly semaglutide versus once-daily sitagliptin as an add-on to metformin, thiazolidinediones, or both, in patients with type 2 diabetes (SUSTAIN 2): a 56-week, double-blind, phase 3a, randomised trial. *Lancet Diabetes Endocrinol*. 2017;5(5):341-54. Epub 20170403. doi: 10.1016/S2213-8587(17)30092-X. PubMed PMID: 28385659.
5. American Diabetes Association Professional Practice Committee. 10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S179-S218. doi: 10.2337/dc24-S010. PubMed PMID: 38078592; PubMed Central PMCID: PMC10725811.
6. American Diabetes Association Professional Practice Committee. 11. Chronic Kidney Disease and Risk Management: Standards of Care in Diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S219-S30. doi: 10.2337/dc24-S011. PubMed PMID: 38078574; PubMed Central PMCID: PMC10725805.
7. American Diabetes Association Professional Practice Committee. 13. Older Adults: Standards of Care in Diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S244-S57. doi: 10.2337/dc24-S013. PubMed PMID: 38078580; PubMed Central PMCID: PMC10725804.
8. American Diabetes Association Professional Practice Committee. 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes-2024. *Diabetes Care*. 2024;47(Suppl

- 1):S20-S42. doi: 10.2337/dc24-S002. PubMed PMID: 38078589; PubMed Central PMCID: PMC10725812.
9. American Diabetes Association Professional Practice Committee. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S158-S78. doi: 10.2337/dc24-S009. PubMed PMID: 38078590; PubMed Central PMCID: PMC10725810.
10. American Diabetes Association. 7. Approaches to glycemic treatment. *Diabetes Care*. 2015;38 Suppl:S41-8. doi: 10.2337/dc15-S010. PubMed PMID: 25537707.
11. American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. *Diabetes Care*. 2018;41(5):917-28. Epub 20180322. doi: 10.2337/dci18-0007. PubMed PMID: 29567642; PubMed Central PMCID: PMC5911784.
12. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. *J Am Geriatr Soc*. 2023;71(7):2052-81. Epub 20230504. doi: 10.1111/jgs.18372. PubMed PMID: 37139824.
13. Arechavaleta R, Seck T, Chen Y, Krobot KJ, O'Neill EA, Duran L, et al. Efficacy and safety of treatment with sitagliptin or glimepiride in patients with type 2 diabetes inadequately controlled on metformin monotherapy: a randomized, double-blind, non-inferiority trial. *Diabetes Obes Metab*. 2011;13(2):160-8. doi: 10.1111/j.1463-1326.2010.01334.x. PubMed PMID: 21199268.
14. Aschner P, Katzeff HL, Guo H, Sunga S, Williams-Herman D, Kaufman KD, et al. Efficacy and safety of monotherapy of sitagliptin compared with metformin in patients with type 2 diabetes. *Diabetes Obes Metab*. 2010;12(3):252-61. Epub 20091125. doi: 10.1111/j.1463-1326.2009.01187.x. PubMed PMID: 20070351.
15. Aschner P, Kipnes MS, Lunceford JK, Sanchez M, Mickel C, Williams-Herman DE. Effect of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy on glycemic control in patients with type 2 diabetes. *Diabetes Care*. 2006;29(12):2632-7. doi: 10.2337/dc06-0703. PubMed PMID: 17130196.
16. AstraZeneca Pharmaceuticals LP. Farxiga (dapagliflozin) [package insert]. U.S. Food and Drug Administration. 2023 Sep. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/202293s030lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202293s030lbl.pdf).
17. Bailey RA, Wang Y, Zhu V, Rupnow MF. Chronic kidney disease in US adults with type 2 diabetes: an updated national estimate of prevalence based on Kidney Disease: Improving Global Outcomes (KDIGO) staging. *BMC Res Notes*. 2014;7:415. Epub 20140702. doi: 10.1186/1756-0500-7-415. PubMed PMID: 24990184; PubMed Central PMCID: PMC4091951.
18. Barzilai N, Guo H, Mahoney EM, Caporossi S, Golm GT, Langdon RB, et al. Efficacy and tolerability of sitagliptin monotherapy in elderly patients with type 2 diabetes: a randomized, double-blind, placebo-controlled trial. *Curr Med Res Opin*. 2011;27(5):1049-58. Epub 20110323. doi: 10.1185/03007995.2011.568059. PubMed PMID: 21428727.
19. Bennett WL, Maruthur NM, Singh S, Segal JB, Wilson LM, Chatterjee R, et al. Comparative effectiveness and safety of medications for type 2 diabetes: an update including new drugs and 2-drug combinations. *Ann Intern Med*. 2011;154(9):602-13. Epub 20110314. doi: 10.7326/0003-4819-154-9-201105030-00336. PubMed PMID: 21403054; PubMed Central PMCID: PMC3733115.
20. Bergenstal RM, Wysham C, Macconell L, Malloy J, Walsh B, Yan P, et al. Efficacy and safety of exenatide once weekly versus sitagliptin or pioglitazone as an adjunct to metformin for treatment of type 2 diabetes (DURATION-2): a randomised trial. *Lancet*.

- 2010;376(9739):431-9. Epub 20100626. doi: 10.1016/S0140-6736(10)60590-9. PubMed PMID: 20580422.
21. Bethel MA, Engel SS, Green JB, Huang Z, Josse RG, Kaufman KD, et al. Assessing the Safety of Sitagliptin in Older Participants in the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS). *Diabetes Care*. 2017;40(4):494-501. Epub 20170105. doi: 10.2337/dc16-1135. PubMed PMID: 28057693.
  22. Blonde L, Umpierrez GE, Reddy SS, McGill JB, Berga SL, Bush M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update. *Endocr Pract*. 2022;28(10):923-1049. Epub 20220811. doi: 10.1016/j.eprac.2022.08.002. PubMed PMID: 35963508; PubMed Central PMCID: PMC10200071.
  23. Boehringer Ingelheim Pharmaceuticals, Inc. Jardiance (empagliflozin) [package insert]. U.S. Food and Drug Administration. 2023 Sep. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/204629s040lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s040lbl.pdf).
  24. Boehringer Ingelheim Pharmaceuticals, Inc. Tradjenta (linagliptin) [package insert]. U.S. Food and Drug Administration. Revised 2023 Jun. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/201280s027lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201280s027lbl.pdf).
  25. Boehringer Ingelheim. The Effect of Linagliptin (BI 1356) on 24h-glucose Control and Various Biomarkers in Type 2 Diabetic Patients. National Library of Medicine; 2014 Jun 27. Report No. NCT00716092. Available from: <https://clinicaltrials.gov/study/NCT00716092?tab=results>.
  26. Bristol-Myers Squibb. Glucophage, Glucophage XR (metformin hydrochloride) [package insert]. U.S. Food and Drug Administration. Revised 2018 May. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/020357s034,021202s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020357s034,021202s018lbl.pdf).
  27. Charbonnel B, Karasik A, Liu J, Wu M, Meininger G. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin added to ongoing metformin therapy in patients with type 2 diabetes inadequately controlled with metformin alone. *Diabetes Care*. 2006;29(12):2638-43. doi: 10.2337/dc06-0706. PubMed PMID: 17130197.
  28. Chong S, Ding D, Byun R, Comino E, Bauman A, Jalaludin B. Lifestyle Changes After a Diagnosis of Type 2 Diabetes. *Diabetes Spectr*. 2017;30(1):43-50. doi: 10.2337/ds15-0044. PubMed PMID: 28270714; PubMed Central PMCID: PMC5309903.
  29. Craddy P, Palin HJ, Johnson KI. Comparative effectiveness of dipeptidylpeptidase-4 inhibitors in type 2 diabetes: a systematic review and mixed treatment comparison. *Diabetes Ther*. 2014;5(1):1-41. Epub 20140325. doi: 10.1007/s13300-014-0061-3. PubMed PMID: 24664619; PubMed Central PMCID: PMC4065303.
  30. de Araújo NC, Silveira EA, Mota BG, Guimarães RA, Modesto ACF, Pagotto V. Risk factors for potentially inappropriate medication use in older adults: a cohort study. *Int J Clin Pharm*. 2022;44(5):1132-9. Epub 20220727. doi: 10.1007/s11096-022-01433-4. PubMed PMID: 35896907.
  31. de Wit HM, Te Groen M, Rovers MM, Tack CJ. The placebo response of injectable GLP-1 receptor agonists vs. oral DPP-4 inhibitors and SGLT-2 inhibitors: a systematic review and meta-analysis. *Br J Clin Pharmacol*. 2016;82(1):301-14. Epub 20160422. doi: 10.1111/bcp.12925. PubMed PMID: 26935973; PubMed Central PMCID: PMC4917794.
  32. Del Prato S, Barnett AH, Huisman H, Neubacher D, Woerle HJ, Dugi KA. Effect of linagliptin monotherapy on glycaemic control and markers of  $\beta$ -cell function in patients with inadequately controlled type 2 diabetes: a randomized controlled trial. *Diabetes Obes*

- Metab. 2011;13(3):258-67. doi: 10.1111/j.1463-1326.2010.01350.x. PubMed PMID: 21205122.
33. Desai U, Kirson NY, Kim J, Khunti K, King S, Trieschman E, et al. Time to Treatment Intensification After Monotherapy Failure and Its Association With Subsequent Glycemic Control Among 93,515 Patients With Type 2 Diabetes. *Diabetes Care*. 2018;41(10):2096-104. Epub 20180821. doi: 10.2337/dc17-0662. PubMed PMID: 30131396.
  34. Doucet J, Gourdy P, Meyer L, Benabdelmoumene N, Bourdel-Marchasson I. Management of Glucose-Lowering Therapy in Older Adults with Type 2 Diabetes: Challenges and Opportunities. *Clin Interv Aging*. 2023;18:1687-703. Epub 20231009. doi: 10.2147/CIA.S423122. PubMed PMID: 37841649; PubMed Central PMCID: PMC10573466.
  35. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. 10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S158-s90. doi: 10.2337/dc23-S010. PubMed PMID: 36507632; PubMed Central PMCID: PMC9810475.
  36. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. 13. Older Adults: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S216-S29. doi: 10.2337/dc23-S013. PubMed PMID: 36507638; PubMed Central PMCID: PMC9810468.
  37. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. 6. Glycemic Targets: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S97-s110. doi: 10.2337/dc23-S006. PubMed PMID: 36507646; PubMed Central PMCID: PMC9810469.
  38. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, et al. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S140-s57. doi: 10.2337/dc23-S009. PubMed PMID: 36507650; PubMed Central PMCID: PMC9810476.
  39. Esposito K, Chiodini P, Capuano A, Maiorino MI, Bellastella G, Giugliano D. Baseline glycemic parameters predict the hemoglobin A1c response to DPP-4 inhibitors : meta-regression analysis of 78 randomized controlled trials with 20,053 patients. *Endocrine*. 2014;46(1):43-51. Epub 20131120. doi: 10.1007/s12020-013-0090-0. PubMed PMID: 24248503.
  40. Fang M, Wang D, Coresh J, Selvin E. Trends in Diabetes Treatment and Control in U.S. Adults, 1999-2018. *N Engl J Med*. 2021;384(23):2219-28. doi: 10.1056/NEJMsa2032271. PubMed PMID: 34107181; PubMed Central PMCID: PMC8385648.
  41. FDA Listing of Established Pharmacologic Class Text Phrases January 2021. U.S. Food and Drug Administration; 2021 Jan. Available from: <https://www.fda.gov/media/144963/download>.
  42. Flaxman AD, Wittenborn JS, Robalik T, Gulia R, Gerzoff RB, Lundeen EA, et al. Prevalence of Visual Acuity Loss or Blindness in the US: A Bayesian Meta-analysis. *JAMA Ophthalmol*. 2021;139(7):717-23. doi: 10.1001/jamaophthalmol.2021.0527. PubMed PMID: 33983373; PubMed Central PMCID: PMC8120442.
  43. Gomes MB, Rathmann W, Charbonnel B, Khunti K, Kosiborod M, Nicolucci A, et al. Treatment of type 2 diabetes mellitus worldwide: Baseline patient characteristics in the global DISCOVER study. *Diabetes Res Clin Pract*. 2019;151:20-32. Epub 20190320. doi: 10.1016/j.diabres.2019.03.024. PubMed PMID: 30904743.
  44. Gomez-Peralta F, Abreu C, Gomez-Rodriguez S, Barranco RJ, Umpierrez GE. Safety and Efficacy of DPP4 Inhibitor and Basal Insulin in Type 2 Diabetes: An Updated Review and Challenging Clinical Scenarios. *Diabetes Ther*. 2018;9(5):1775-89. Epub 20180816. doi: 10.1007/s13300-018-0488-z. PubMed PMID: 30117055; PubMed Central PMCID: PMC6167285.

45. Green JB, Bethel MA, Armstrong PW, Buse JB, Engel SS, Garg J, et al. Effect of Sitagliptin on Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med*. 2015;373(3):232-42. Epub 20150608. doi: 10.1056/NEJMoa1501352. PubMed PMID: 26052984.
46. Hartley P, Shentu Y, Betz-Schiff P, Golm GT, Sisk CM, Engel SS, et al. Efficacy and Tolerability of Sitagliptin Compared with Glimepiride in Elderly Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control: A Randomized, Double-Blind, Non-Inferiority Trial. *Drugs Aging*. 2015;32(6):469-76. doi: 10.1007/s40266-015-0271-z. PubMed PMID: 26041585.
47. Holstein A, Hammer C, Hahn M, Kulamadayil NS, Kovacs P. Severe sulfonylurea-induced hypoglycemia: a problem of uncritical prescription and deficiencies of diabetes care in geriatric patients. *Expert Opin Drug Saf*. 2010;9(5):675-81. doi: 10.1517/14740338.2010.492777. PubMed PMID: 20553106.
48. Iglay K, Hannachi H, Joseph Howie P, Xu J, Li X, Engel SS, et al. Prevalence and co-prevalence of comorbidities among patients with type 2 diabetes mellitus. *Curr Med Res Opin*. 2016;32(7):1243-52. Epub 20160404. doi: 10.1185/03007995.2016.1168291. PubMed PMID: 26986190.
49. Institute of Medicine of the National Academies. Initial National Priorities for Comparative Effectiveness Research. The National Academies Press; 2009.
50. Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*. 2012;35(6):1364-79. Epub 20120419. doi: 10.2337/dc12-0413. PubMed PMID: 22517736; PubMed Central PMCID: PMC3357214.
51. Januvia (sitagliptin phosphate) [FDA approval letter]. U.S. Food and Drug Administration; 2006 Oct 16. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2006/021995s000\\_APPROV.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021995s000_APPROV.pdf).
52. Jia Y, Lao Y, Zhu H, Li N, Leung SW. Is metformin still the most efficacious first-line oral hypoglycaemic drug in treating type 2 diabetes? A network meta-analysis of randomized controlled trials. *Obes Rev*. 2019;20(1):1-12. Epub 20180917. doi: 10.1111/obr.12753. PubMed PMID: 30230172.
53. Kandelaki K, Marrone G, Lundborg CS, Schmidt I, Björkman I. Patient-centredness as a quality domain in Swedish healthcare: results from the first national surveys in different Swedish healthcare settings. *BMJ Open*. 2016;6(1):e009056. Epub 20160108. doi: 10.1136/bmjopen-2015-009056. PubMed PMID: 26747031; PubMed Central PMCID: PMC4716147.
54. Kantor ED, Rehm CD, Haas JS, Chan AT, Giovannucci EL. Trends in Prescription Drug Use Among Adults in the United States From 1999-2012. *Jama*. 2015;314(17):1818-31. doi: 10.1001/jama.2015.13766. PubMed PMID: 26529160; PubMed Central PMCID: PMC4752169.
55. Keshavarz K, Lotfi F, Sanati E, Salesi M, Hashemi-Meshkini A, Jafari M, et al. Linagliptin versus sitagliptin in patients with type 2 diabetes mellitus: a network meta-analysis of randomized clinical trials. *Daru*. 2017;25(1):23. Epub 20171025. doi: 10.1186/s40199-017-0189-6. PubMed PMID: 29070077; PubMed Central PMCID: PMC5655990.
56. Laiteerapong N, Ham SA, Gao Y, Moffet HH, Liu JY, Huang ES, et al. The Legacy Effect in Type 2 Diabetes: Impact of Early Glycemic Control on Future Complications (The Diabetes & Aging Study). *Diabetes Care*. 2019;42(3):416-26. Epub 20180813. doi: 10.2337/dc17-1144. PubMed PMID: 30104301; PubMed Central PMCID: PMC6385699.
57. Landon BE, Zaslavsky AM, Souza J, Ayanian JZ. Trends in Diabetes Treatment and Monitoring among Medicare Beneficiaries. *J Gen Intern Med*. 2018;33(4):471-80. Epub 20180209. doi:

- 10.1007/s11606-018-4310-4. PubMed PMID: 29427177; PubMed Central PMCID: PMC5880782.
58. Li Y, Hu Y, Ley SH, Rajpathak S, Hu FB. Sulfonylurea use and incident cardiovascular disease among patients with type 2 diabetes: prospective cohort study among women. *Diabetes Care*. 2014;37(11):3106-13. Epub 20140822. doi: 10.2337/dc14-1306. PubMed PMID: 25150157; PubMed Central PMCID: PMC4207206.
  59. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *Bmj*. 2009;339:b2700. Epub 20090721. doi: 10.1136/bmj.b2700. PubMed PMID: 19622552; PubMed Central PMCID: PMC2714672.
  60. Ling J, Cheng P, Ge L, Zhang DH, Shi AC, Tian JH, et al. The efficacy and safety of dipeptidyl peptidase-4 inhibitors for type 2 diabetes: a Bayesian network meta-analysis of 58 randomized controlled trials. *Acta Diabetol*. 2019;56(3):249-72. Epub 20180921. doi: 10.1007/s00592-018-1222-z. PubMed PMID: 30242726.
  61. Liu X, Xiao Q, Zhang L, Yang Q, Liu X, Xu L, et al. The long-term efficacy and safety of DPP-IV inhibitors monotherapy and in combination with metformin in 18,980 patients with type-2 diabetes mellitus--a meta-analysis. *Pharmacoepidemiol Drug Saf*. 2014;23(7):687-98. Epub 20140318. doi: 10.1002/pds.3586. PubMed PMID: 24639059.
  62. Longo M, Bellastella G, Maiorino MI, Meier JJ, Esposito K, Giugliano D. Diabetes and Aging: From Treatment Goals to Pharmacologic Therapy. *Front Endocrinol (Lausanne)*. 2019;10:45. Epub 20190218. doi: 10.3389/fendo.2019.00045. PubMed PMID: 30833929; PubMed Central PMCID: PMC6387929.
  63. Maher RL, Hanlon J, Hajjar ER. Clinical consequences of polypharmacy in elderly. *Expert Opin Drug Saf*. 2014;13(1):57-65. Epub 20130927. doi: 10.1517/14740338.2013.827660. PubMed PMID: 24073682; PubMed Central PMCID: PMC3864987.
  64. Maloney A, Rosenstock J, Fonseca V. A Model-Based Meta-Analysis of 24 Antihyperglycemic Drugs for Type 2 Diabetes: Comparison of Treatment Effects at Therapeutic Doses. *Clin Pharmacol Ther*. 2019;105(5):1213-23. Epub 20190113. doi: 10.1002/cpt.1307. PubMed PMID: 30457671.
  65. Manly JJ, Jones RN, Langa KM, Ryan LH, Levine DA, McCammon R, et al. Estimating the Prevalence of Dementia and Mild Cognitive Impairment in the US: The 2016 Health and Retirement Study Harmonized Cognitive Assessment Protocol Project. *JAMA Neurol*. 2022;79(12):1242-9. doi: 10.1001/jamaneurol.2022.3543. PubMed PMID: 36279130; PubMed Central PMCID: PMC9593315.
  66. Matthews DR, Paldanius PM, Proot P, Chiang Y, Stumvoll M, Del Prato S. Glycaemic durability of an early combination therapy with vildagliptin and metformin versus sequential metformin monotherapy in newly diagnosed type 2 diabetes (VERIFY): a 5-year, multicentre, randomised, double-blind trial. *Lancet*. 2019;394(10208):1519-29. Epub 20190918. doi: 10.1016/s0140-6736(19)32131-2. PubMed PMID: 31542292.
  67. Mattishent K, Loke YK. Meta-Analysis: Association Between Hypoglycemia and Serious Adverse Events in Older Patients Treated With Glucose-Lowering Agents. *Front Endocrinol (Lausanne)*. 2021;12:571568. Epub 20210308. doi: 10.3389/fendo.2021.571568. PubMed PMID: 33763024; PubMed Central PMCID: PMC7982741.
  68. McCoy RG, Van Houten HK, Deng Y, Mandic PK, Ross JS, Montori VM, et al. Comparison of Diabetes Medications Used by Adults With Commercial Insurance vs Medicare Advantage, 2016 to 2019. *JAMA Netw Open*. 2021;4(2):e2035792. Epub 20210201. doi:



- 10.1001/jamanetworkopen.2020.35792. PubMed PMID: 33523188; PubMed Central PMCID: PMC7851726.
69. McGuire DK, Alexander JH, Johansen OE, Perkovic V, Rosenstock J, Cooper ME, et al. Linagliptin Effects on Heart Failure and Related Outcomes in Individuals With Type 2 Diabetes Mellitus at High Cardiovascular and Renal Risk in CARMELINA. *Circulation*. 2019;139(3):351-61. doi: 10.1161/circulationaha.118.038352. PubMed PMID: 30586723.
  70. Mearns ES, Sobieraj DM, White CM, Saulsberry WJ, Kohn CG, Doleh Y, et al. Comparative efficacy and safety of antidiabetic drug regimens added to metformin monotherapy in patients with type 2 diabetes: a network meta-analysis. *PLoS One*. 2015;10(4):e0125879. Epub 20150428. doi: 10.1371/journal.pone.0125879. PubMed PMID: 25919293; PubMed Central PMCID: PMC4412636.
  71. Merck Sharp & Dohme LLC. Januvia (sitagliptin) [package insert]. U.S. Food and Drug Administration. Revised 2023 Dec. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/021995Orig1s053lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/021995Orig1s053lbl.pdf).
  72. Moreland B, Kakara R, Henry A. Trends in Nonfatal Falls and Fall-Related Injuries Among Adults Aged ≥65 Years - United States, 2012-2018. *MMWR Morb Mortal Wkly Rep*. 2020;69(27):875-81. Epub 20200710. doi: 10.15585/mmwr.mm6927a5. PubMed PMID: 32644982; PubMed Central PMCID: PMC7732363.
  73. Mullard A. 2016 FDA drug approvals. *Nat Rev Drug Discov*. 2017;16(2):73-6. doi: 10.1038/nrd.2017.14. PubMed PMID: 28148938.
  74. Mylan Pharmaceuticals Inc. Saxagliptin [package insert]. U.S. Food and Drug Administration. Revised 2023 Apr. Available from: <https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=6e8d8c4f-96eb-4b64-9c8c-4a5448a23a78&type=pdf>.
  75. National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Health and Economic Benefits of Diabetes Interventions [Internet]. Georgia: U.S. Centers for Disease Control and Prevention [cited 2023 Oct 26]. Available from: <https://www.cdc.gov/nccdphp/priorities/diabetes-interventions.html>.
  76. National Diabetes Statistics Report [Internet]. Georgia: U.S. Centers for Disease Control and Prevention; [cited 2023 Jun 5]. Available from: <https://www.cdc.gov/diabetes/php/data-research/index.html>.
  77. Nauck M, Weinstock RS, Umpierrez GE, Guerci B, Skrivanek Z, Milicevic Z. Efficacy and safety of dulaglutide versus sitagliptin after 52 weeks in type 2 diabetes in a randomized controlled trial (AWARD-5). *Diabetes Care*. 2014;37(8):2149-58. Epub 20140417. doi: 10.2337/dc13-2761. PubMed PMID: 24742660; PubMed Central PMCID: PMC4113177.
  78. Nauck MA, Meininger G, Sheng D, Terranella L, Stein PP, Sitagliptin Study 024 Group. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor, sitagliptin, compared with the sulfonylurea, glipizide, in patients with type 2 diabetes inadequately controlled on metformin alone: a randomized, double-blind, non-inferiority trial. *Diabetes Obes Metab*. 2007;9(2):194-205. doi: 10.1111/j.1463-1326.2006.00704.x. PubMed PMID: 17300595.
  79. Nitzan O, Elias M, Chazan B, Saliba W. Urinary tract infections in patients with type 2 diabetes mellitus: review of prevalence, diagnosis, and management. *Diabetes Metab Syndr Obes*. 2015;8:129-36. Epub 20150226. doi: 10.2147/dmso.S51792. PubMed PMID: 25759592; PubMed Central PMCID: PMC4346284.
  80. Office of Health Policy. Inflation Reduction Act research series: Medicare enrollees' use and out-of-pocket expenditures for drugs selected for negotiation under the Medicare Drug Price Negotiation Program. Assistant Secretary for Planning and Evaluation (ASPE); 2023 Aug 29. Report No. HP-2023-21. Available from:

<https://aspe.hhs.gov/sites/default/files/documents/23148a5897ea92a142aab21e2ec29ca2/ASPE-IRA-Drug-Negotiation-Fact-Sheet.pdf>.

81. Ogundipe O, Mazidi M, Chin KL, Gor D, McGovern A, Sahle BW, et al. Real-world adherence, persistence, and in-class switching during use of dipeptidyl peptidase-4 inhibitors: a systematic review and meta-analysis involving 594,138 patients with type 2 diabetes. *Acta Diabetol.* 2021;58(1):39-46. Epub 20200818. doi: 10.1007/s00592-020-01590-w. PubMed PMID: 32809070.
82. Padagis Israel Pharmaceuticals Ltd. Alogliptin [package insert]. U.S. Food and Drug Administration. Revised 2023 Jul. Available from: <https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=b25f155a-1259-47c2-aa3b-7c1356e4c7f6&type=pdf>.
83. Pantalone KM, Wells BJ, Chagin KM, Ejzykowicz F, Yu C, Milinovich A, et al. Intensification of Diabetes Therapy and Time Until A1C Goal Attainment Among Patients With Newly Diagnosed Type 2 Diabetes Who Fail Metformin Monotherapy Within a Large Integrated Health System. *Diabetes Care.* 2016;39(9):1527-34. Epub 20160812. doi: 10.2337/dc16-0227. PubMed PMID: 27519447.
84. Petri H, Urquhart J. Channeling bias in the interpretation of drug effects. *Stat Med.* 1991;10(4):577-81. doi: 10.1002/sim.4780100409. PubMed PMID: 2057656.
85. Pieber TR, Bode B, Mertens A, Cho YM, Christiansen E, Hertz CL, et al. Efficacy and safety of oral semaglutide with flexible dose adjustment versus sitagliptin in type 2 diabetes (PIONEER 7): a multicentre, open-label, randomised, phase 3a trial. *Lancet Diabetes Endocrinol.* 2019;7(7):528-39. Epub 20190609. doi: 10.1016/S2213-8587(19)30194-9. PubMed PMID: 31189520.
86. Rajpathak SN, Fu C, Brodovicz KG, Engel SS, Lapane K. Sulfonylurea use and risk of hip fractures among elderly men and women with type 2 diabetes. *Drugs Aging.* 2015;32(4):321-7. doi: 10.1007/s40266-015-0254-0. PubMed PMID: 25825122.
87. Rauch T, Graefe-Mody U, Deacon CF, Ring A, Holst JJ, Woerle HJ, et al. Linagliptin increases incretin levels, lowers glucagon, and improves glycemic control in type 2 diabetes mellitus. *Diabetes Ther.* 2012;3(1):10. Epub 20120918. doi: 10.1007/s13300-012-0010-y. PubMed PMID: 22986920; PubMed Central PMCID: PMC3508116.
88. Raz I, Chen Y, Wu M, Hussain S, Kaufman KD, Amatruda JM, et al. Efficacy and safety of sitagliptin added to ongoing metformin therapy in patients with type 2 diabetes. *Curr Med Res Opin.* 2008;24(2):537-50. doi: 10.1185/030079908x260925. PubMed PMID: 18194595.
89. Raz I, Hanefeld M, Xu L, Caria C, Williams-Herman D, Khatami H. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy in patients with type 2 diabetes mellitus. *Diabetologia.* 2006;49(11):2564-71. Epub 20060926. doi: 10.1007/s00125-006-0416-z. PubMed PMID: 17001471.
90. Roden M, Weng J, Eilbracht J, Delafont B, Kim G, Woerle HJ, et al. Empagliflozin monotherapy with sitagliptin as an active comparator in patients with type 2 diabetes: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Diabetes Endocrinol.* 2013;1(3):208-19. Epub 20130909. doi: 10.1016/S2213-8587(13)70084-6. PubMed PMID: 24622369.
91. Rodriguez-Mañas L. Urinary tract infections in the elderly: a review of disease characteristics and current treatment options. *Drugs Context.* 2020;9. Epub 20200708. doi: 10.7573/dic.2020-4-13. PubMed PMID: 32699546; PubMed Central PMCID: PMC7357682.
92. Rosenstock J, Allison D, Birkenfeld AL, Blicher TM, Deenadayalan S, Jacobsen JB, et al. Effect of Additional Oral Semaglutide vs Sitagliptin on Glycated Hemoglobin in Adults With Type 2 Diabetes Uncontrolled With Metformin Alone or With Sulfonylurea: The PIONEER 3

- Randomized Clinical Trial. JAMA. 2019;321(15):1466-80. doi: 10.1001/jama.2019.2942. PubMed PMID: 30903796; PubMed Central PMCID: PMC6484814.
93. Rosenstock J, Perkovic V, Alexander JH, Cooper ME, Marx N, Pencina MJ, et al. Rationale, design, and baseline characteristics of the CARDiovascular safety and Renal Microvascular outcomE study with LINAgliptin (CARMELINA<sup>®</sup>): a randomized, double-blind, placebo-controlled clinical trial in patients with type 2 diabetes and high cardio-renal risk. Cardiovasc Diabetol. 2018;17(1):39. Epub 20180314. doi: 10.1186/s12933-018-0682-3. PubMed PMID: 29540217; PubMed Central PMCID: PMC5870815.
  94. Round EM, Engel SS, Golm GT, Davies MJ, Kaufman KD, Goldstein BJ. Safety of sitagliptin in elderly patients with type 2 diabetes: a pooled analysis of 25 clinical studies. Drugs Aging. 2014;31(3):203-14. doi: 10.1007/s40266-014-0155-7. PubMed PMID: 24510656.
  95. Salvo F, Moore N, Arnaud M, Robinson P, Raschi E, De Ponti F, et al. Addition of dipeptidyl peptidase-4 inhibitors to sulphonylureas and risk of hypoglycaemia: systematic review and meta-analysis. Bmj. 2016;353:i2231. Epub 20160503. doi: 10.1136/bmj.i2231. PubMed PMID: 27142267; PubMed Central PMCID: PMC4854021.
  96. Samson SL, Vellanki P, Blonde L, Christofides EA, Galindo RJ, Hirsch IB, et al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm - 2023 Update. Endocr Pract. 2023;29(5):305-40. doi: 10.1016/j.eprac.2023.02.001. PubMed PMID: 37150579.
  97. Schernthaner G, Barnett AH, Patel S, Hehnke U, von Eynatten M, Woerle HJ. Safety and efficacy of the dipeptidyl peptidase-4 inhibitor linagliptin in elderly patients with type 2 diabetes: a comprehensive analysis of data from 1331 individuals aged  $\geq 65$  years. Diabetes Obes Metab. 2014;16(11):1078-86. Epub 20140703. doi: 10.1111/dom.12321. PubMed PMID: 24865132.
  98. Schlender L, Martinez YV, Adeniji C, Reeves D, Faller B, Sommerauer C, et al. Efficacy and safety of metformin in the management of type 2 diabetes mellitus in older adults: a systematic review for the development of recommendations to reduce potentially inappropriate prescribing. BMC Geriatr. 2017;17(Suppl 1):227. Epub 20171016. doi: 10.1186/s12877-017-0574-5. PubMed PMID: 29047344; PubMed Central PMCID: PMC5647555.
  99. Scirica BM, Bhatt DL, Braunwald E, Steg PG, Davidson J, Hirshberg B, et al. Saxagliptin and cardiovascular outcomes in patients with type 2 diabetes mellitus. N Engl J Med. 2013;369(14):1317-26. Epub 20130902. doi: 10.1056/NEJMoa1307684. PubMed PMID: 23992601.
  100. Scott R, Loeys T, Davies MJ, Engel SS. Efficacy and safety of sitagliptin when added to ongoing metformin therapy in patients with type 2 diabetes. Diabetes Obes Metab. 2008;10(10):959-69. Epub 20080114. doi: 10.1111/j.1463-1326.2007.00839.x. PubMed PMID: 18201203.
  101. Shi Q, Nong K, Vandvik PO, Guyatt GH, Schnell O, Ryden L, et al. Benefits and harms of drug treatment for type 2 diabetes: systematic review and network meta-analysis of randomised controlled trials. BMJ. 2023;381:e074068. Epub 20230406. doi: 10.1136/bmj-2022-074068. PubMed PMID: 37024129; PubMed Central PMCID: PMC10077111.
  102. Sikirica MV, Martin AA, Wood R, Leith A, Piercy J, Higgins V. Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes. Diabetes Metab Syndr Obes. 2017;10:403-12. Epub 20170929. doi: 10.2147/dmso.S141235. PubMed PMID: 29033597; PubMed Central PMCID: PMC5630073.

103. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *Bmj*. 2000;321(7258):405-12. doi: 10.1136/bmj.321.7258.405. PubMed PMID: 10938048; PubMed Central PMCID: PMC27454.
104. Tago M, Oyama JI, Sakamoto Y, Shiraki A, Uchida F, Chihara A, et al. Efficacy and safety of sitagliptin in elderly patients with type 2 diabetes mellitus. *Geriatr Gerontol Int*. 2018;18(4):631-9. Epub 20180104. doi: 10.1111/ggi.13235. PubMed PMID: 29314506.
105. Takeda Pharmaceuticals America, Inc. Nesina (alogliptin) [package insert]. U.S. Food and Drug Administration. Revised 2023 Jul. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/022271s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022271s015lbl.pdf).
106. Tarazi W, Welch WP, Nguyen N, Bosworth A, Sheingold S, De Lew N, et al. Medicare Beneficiary Enrollment Trends and Demographic Characteristics. Assistant Secretary for Planning and Evaluation; 2022 Mar 2. Available from: <https://aspe.hhs.gov/sites/default/files/documents/b9ac26a13b4fdf30c16c24e79df0c99c/medicare-beneficiary-enrollment-ib.pdf>.
107. Taskinen MR, Rosenstock J, Tamminen I, Kubiak R, Patel S, Dugi KA, et al. Safety and efficacy of linagliptin as add-on therapy to metformin in patients with type 2 diabetes: a randomized, double-blind, placebo-controlled study. *Diabetes Obes Metab*. 2011;13(1):65-74. doi: 10.1111/j.1463-1326.2010.01326.x. PubMed PMID: 21114605.
108. Tsapas A, Avgerinos I, Karagiannis T, Malandris K, Manolopoulos A, Andreadis P, et al. Comparative Effectiveness of Glucose-Lowering Drugs for Type 2 Diabetes: A Systematic Review and Network Meta-analysis. *Ann Intern Med*. 2020;173(4):278-86. Epub 20200630. doi: 10.7326/M20-0864. PubMed PMID: 32598218.
109. Type 2 Diabetes [Internet]. U.S. Centers for Disease Control and Prevention [cited 2023 Aug 25]. Available from: <https://www.cdc.gov/diabetes/about/about-type-2-diabetes.html>.
110. Uitrakul S, Aksonnam K, Srivichai P, Wicheannarat S, Incomenoy S. The Incidence and Risk Factors of Urinary Tract Infection in Patients with Type 2 Diabetes Mellitus Using SGLT2 Inhibitors: A Real-World Observational Study. *Medicines (Basel)*. 2022;9(12). Epub 20221122. doi: 10.3390/medicines9120059. PubMed PMID: 36547992; PubMed Central PMCID: PMC9785475.
111. Wang T, McNeill AM, Chen Y, O'Neill EA, Engel SS. Characteristics of Elderly Patients Initiating Sitagliptin or Non-DPP-4-Inhibitor Oral Antihyperglycemic Agents: Analysis of a Cross-Sectional US Claims Database. *Diabetes Ther*. 2018;9(1):309-15. Epub 20180112. doi: 10.1007/s13300-017-0360-6. PubMed PMID: 29330813; PubMed Central PMCID: PMC5801246.
112. Wang Y, Zhu J, Shan L, Wu L, Wang C, Yang W. Potentially inappropriate medication among older patients with diabetic kidney disease. *Front Pharmacol*. 2023;14:1098465. Epub 20230208. doi: 10.3389/fphar.2023.1098465. PubMed PMID: 36843920; PubMed Central PMCID: PMC9946453.
113. White WB, Cannon CP, Heller SR, Nissen SE, Bergenstal RM, Bakris GL, et al. Alogliptin after acute coronary syndrome in patients with type 2 diabetes. *N Engl J Med*. 2013;369(14):1327-35. Epub 20130902. doi: 10.1056/NEJMoa1305889. PubMed PMID: 23992602.
114. Wu CY, Iskander C, Wang C, Xiong LY, Shah BR, Edwards JD, et al. Association of sulfonylureas with the risk of dementia: A population-based cohort study. *J Am Geriatr Soc*. 2023;71(10):3059-70. Epub 20230522. doi: 10.1111/jgs.18397. PubMed PMID: 37218376.
115. Wu D, Li L, Liu C. Efficacy and safety of dipeptidyl peptidase-4 inhibitors and metformin as initial combination therapy and as monotherapy in patients with type 2 diabetes mellitus: a

- meta-analysis. *Diabetes Obes Metab*. 2014;16(1):30-7. Epub 20130716. doi: 10.1111/dom.12174. PubMed PMID: 23803146.
116. Yang H, Choi E, Park E, Na E, Chung SY, Kim B, et al. Risk of genital and urinary tract infections associated with SGLT-2 inhibitors as an add-on therapy to metformin in patients with type 2 diabetes mellitus: A retrospective cohort study in Korea. *Pharmacol Res Perspect*. 2022;10(1):e00910. doi: 10.1002/prp2.910. PubMed PMID: 35005849; PubMed Central PMCID: PMC8929338.
117. Zannad F, Cannon CP, Cushman WC, Bakris GL, Menon V, Perez AT, et al. Heart failure and mortality outcomes in patients with type 2 diabetes taking alogliptin versus placebo in EXAMINE: a multicentre, randomised, double-blind trial. *Lancet*. 2015;385(9982):2067-76. Epub 20150310. doi: 10.1016/s0140-6736(14)62225-x. PubMed PMID: 25765696.

## Redacted Negotiation Meeting Summaries for Januvia

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.



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**SUBJECT:** Meeting Summary from Negotiation Meeting between the Centers for Medicare & Medicaid Services (CMS) and Merck Sharp Dohme regarding Januvia on April 22, 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. Merck Sharp Dohme (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Januvia (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 22, 2024 between 11:00 AM ET and 1:30 PM ET.

**CMS Attendees:**

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

**Primary Manufacturer Attendees:**

- 1.
- 2.
- 3.
- 4.
- 5.

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

- Introductions and meeting reminders
- Discussion of initial offer and any questions from the Primary Manufacturer
- Discussion of counteroffer and any questions from CMS
- Any other considerations that CMS and the Primary Manufacturer would like to discuss
- Next steps

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



**Offers/Counteroffers Exchanged:**





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**SUBJECT:** Meeting Summary from Negotiation Meeting between the Centers for Medicare & Medicaid Services (CMS) and Merck Sharp Dohme regarding Januvia on May 29, 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. Merck Sharp Dohme (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Januvia (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 22, 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 May 29, 2024 between 10:00 AM ET and 12:30 PM ET.

**CMS Attendees:**

1. Kristie Gurley, Representative from the Office of the General Counsel
2. Dan Heider, Director, Division of Rebate Agreements and Drug Price Negotiation
3. Tina Li, Medicare Drug Rebate and Negotiations Group
4. Nisha Mehta, Division of Rebate Agreements and Drug Price Negotiation
5. Steven Selde, Division of Rebate Agreements and Drug Price Negotiation
6. Lara Strawbridge, Deputy Director of Policy, Medicare Drug Rebate and Negotiations Group

**Primary Manufacturer Attendees:**

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

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

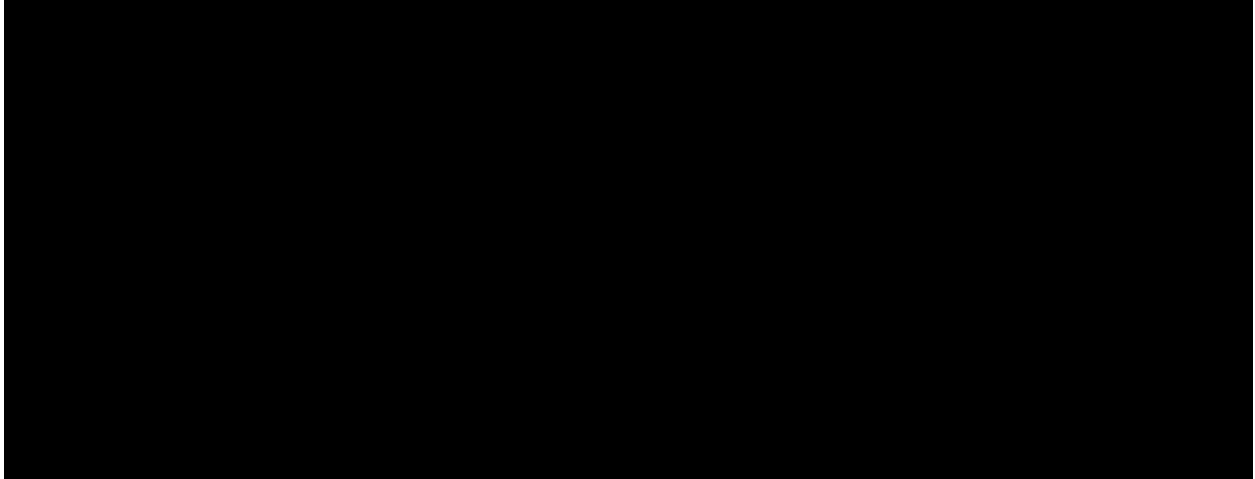
- Introductions and meeting reminders
- Any additional comparative clinical evidence not covered in prior meeting
- Further discussion of commercial average net price

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

- Any additional considerations from Primary Manufacturer related to beneficiary access concerns previously shared with CMS
- Any other considerations that CMS or the Primary Manufacturer would like to discuss
  - Potential for revised therapeutic alternative basket/impact on CMS offer
  - CMS counter-offer next steps
- Next steps

**Offers/Counteroffers Exchanged:**





**SUBJECT:** Meeting Summary from Negotiation Meeting between the Centers for Medicare & Medicaid Services (CMS) and Merck Sharp Dohme regarding Januvia on June 26, 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. Merck Sharp Dohme (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Januvia (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 May 29, 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 26, 2024, between 10:00 AM ET and 12:30 PM ET.

**CMS Attendees:**

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

**Primary Manufacturer Attendees:**

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

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

- Introductions and meeting reminders
- Revised offer/counteroffer price discussion

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<sup>1</sup> 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:**

