



Maximum Fair Price (MFP) Explanation for Imbruvica

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 Imbruvica for the agreed-upon MFP that resulted from the negotiations for initial price applicability year 2026 with Pharmacyclics LLC, the manufacturer of Imbruvica (the “Primary Manufacturer”), provides information about the negotiations for Imbruvica. 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 Imbruvica.

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 Imbruvica 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

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](#).

process ended in both parties agreeing to an MFP of \$9,319.00 for Imbruvica 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 Imbruvica
 - Summary of the Negotiation Process
 - Indications for Imbruvica
 - Factors Applied
 - Manufacturer-Specific Data
 - Evidence about Imbruvica and Therapeutic Alternatives to Imbruvica
 - Therapeutic Alternatives
 - Outcomes and Additional Considerations
 - Citations to Data Reviewed during the Negotiation Process for Imbruvica
- Redacted Negotiation Meeting Summaries for Imbruvica
- Redacted Data Submitted by the Primary Manufacturer and Other Interested Parties for Imbruvica

MFP Explanation Narrative for Imbruvica

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 Imbruvica. 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

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.

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.

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 Imbruvica 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 Imbruvica in response to the Negotiation Program information collection request
- October 27, 2023: CMS met with the Primary Manufacturer regarding its response to the Negotiation Program information collection request
- November 6, 2023: CMS held a patient-focused listening session for Imbruvica
- 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 26, 2024: CMS and the Primary Manufacturer met for the first negotiation meeting
- May 31, 2024: CMS and the Primary Manufacturer met for the second negotiation meeting
- June 27, 2024: CMS and the Primary Manufacturer met for the third negotiation meeting
- August 1, 2024: The negotiation period ended
- August 15, 2024: MFP of \$9,319.00 was published

Indications for Imbruvica

Imbruvica belongs to a class of medications called kinase inhibitors which help stop the spread of cancer cells. It is used alone or with other drugs to treat adults with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) or Waldenström’s macroglobulinemia (WM), which are types of blood cancer. It is also used to treat adults and children aged 1 year and older with chronic graft versus host disease after being treated unsuccessfully with one or more therapies.⁶

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

| Description of indication | Terminology used in this document |
|--|-----------------------------------|
| <ul style="list-style-type: none"> • Adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) • Adult patients with CLL/SLL with 17p deletion | CLL/SLL |
| <ul style="list-style-type: none"> • Adult patients with Waldenström’s macroglobulinemia | WM |
| <ul style="list-style-type: none"> • Adult and pediatric patients aged 1 year and older with chronic graft versus host disease after failure of one or more lines of systemic therapy | cGVHD |

Table 1. cGVHD = chronic graft versus host disease; WM = Waldenström’s macroglobulinemia. 17p deletion is a genetic mutation that may be observed in some patients with CLL/SLL. For purposes of CMS’ consideration of indications for Imbruvica, 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 Imbruvica.

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.

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

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

- The extent to which Imbruvica 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 Imbruvica and therapeutic alternatives to Imbruvica;
- Comparative effectiveness of Imbruvica and therapeutic alternatives to Imbruvica, taking into consideration the effects of Imbruvica and therapeutic alternatives to Imbruvica on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations; and
- The extent to which Imbruvica and therapeutic alternatives to Imbruvica 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 Imbruvica.

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

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).

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.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 Imbruvica, and other allowable direct costs. CMS also requested the global and U.S. total lifetime net revenue for Imbruvica 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 Imbruvica and current average unit costs of distribution for Imbruvica 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 Imbruvica 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 Imbruvica. For example, CMS applied information on prices for Imbruvica 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 Imbruvica and Therapeutic Alternatives to Imbruvica

CMS considered information related to the negotiation factors regarding evidence about Imbruvica and therapeutic alternatives to Imbruvica. 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-

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](#).

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 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 6, 2023.¹³ Patient input was important to CMS' consideration of the evidence about Imbruvica and therapeutic alternatives to Imbruvica, including to help identify outcomes of interest for patients and to understand additional considerations such as patients' preferences regarding treatment. For example, speakers at the patient-focused listening session shared their appreciation of having access to a diverse array of treatment options, including options with oral routes of administration. This was one consideration among the many that informed CMS' understanding of the factors regarding evidence about Imbruvica 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 Imbruvica to therapeutic alternatives in its determination of offers and consideration of counteroffers for Imbruvica.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 Imbruvica or that these are the only pharmaceutical treatments that might be used by a person with one of the indications treated by Imbruvica. 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 Imbruvica based on a holistic consideration of the available evidence from a range of sources. In addition to the sources listed above,

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.”

¹³ The redacted transcript for this patient-focused listening session is available at the following link: <https://www.cms.gov/files/document/imbruvica-transcript-110623.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](#).

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 |
|------------|--|
| CLL/SLL | <ul style="list-style-type: none"> • Acalabrutinib • Zanubrutinib • Combination regimen of venetoclax with obinutuzumab • Combination regimen of venetoclax with rituximab |
| WM | <ul style="list-style-type: none"> • Zanubrutinib • Combination regimen of bendamustine with rituximab (BR) • Combination regimen of dexamethasone, rituximab, and cyclophosphamide (DRC) |
| cGVHD | <ul style="list-style-type: none"> • Belumosudil • Ruxolitinib |

Table 2. cGVHD = chronic graft versus host disease; CLL/SLL = chronic lymphocytic leukemia/small lymphocytic lymphoma; WM = Waldenström's macroglobulinemia. 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 Imbruvica or that these are the only pharmaceutical treatments that might be used by a person with one of the indications treated by Imbruvica. 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 Imbruvica 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 Imbruvica and therapeutic alternatives to Imbruvica, CMS identified clinically relevant and patient-centered outcomes of interest from the body of available literature to evaluate for each indication of Imbruvica. CMS then identified evidence comparing Imbruvica 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 Imbruvica:

| Indication | Effectiveness Outcomes | Safety Outcomes |
|------------|--|---|
| CLL/SLL | <ul style="list-style-type: none"> Overall survival Progression-free survival Overall response rate | <ul style="list-style-type: none"> Cardiovascular events (e.g., atrial fibrillation, hypertension) Hemorrhage Infection Neutropenia All grade 3-4 adverse events |
| WM | <ul style="list-style-type: none"> Overall survival Progression-free survival Treatment response rate | <ul style="list-style-type: none"> Cardiovascular events (e.g., atrial fibrillation, hypertension) Hemorrhage Infection Neutropenia All grade 3-4 adverse events |
| cGVHD | <ul style="list-style-type: none"> Overall response rate | <ul style="list-style-type: none"> Serious adverse events Tolerability (e.g., discontinuation due to adverse events) |

Table 3. cGVHD = chronic graft versus host disease; CLL/SLL = chronic lymphocytic leukemia/small lymphocytic lymphoma; WM = Waldenström’s macroglobulinemia. Outcomes identified in this table were of interest to CMS in its evaluation of Imbruvica. 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, overall survival and progression-free survival are key outcomes that are often used to evaluate effectiveness of treatments for patients with CLL/SLL or WM. In addition, the risk of adverse events, including atrial fibrillation and hypertension, reflects an important safety consideration when evaluating drugs for these indications.

Additionally, CMS considered the extent to which Imbruvica represents a therapeutic advance as compared to existing therapeutic alternatives, and the extent to which Imbruvica 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 Imbruvica, CMS holistically considered the negotiation factors regarding evidence about Imbruvica and its therapeutic alternatives, including consideration of the clinical benefit of Imbruvica in the context of its therapeutic alternatives. For example, CMS applied its understanding of the comparative effectiveness of Imbruvica and its therapeutic alternatives for each of the identified indications, including, for example, consideration of each therapy’s use in treatment-naïve and previously treated patients with CLL/SLL or WM, when negotiating with the Primary Manufacturer. CMS’ holistic assessment was informed by additional contextual considerations, such as patient subgroups (e.g., children), treatment complexity (e.g., route of administration), FDA safety labeling, and patient preferences.

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 Imbruvica 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 Imbruvica

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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Redacted Negotiation Meeting Summaries for Imbruvica

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 Pharmacyclics LLC regarding Imbruvica on April 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. Pharmacyclics LLC (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Imbruvica (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 26, 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. Emily Shaw, Representative from the Office of the General Counsel
6. Lara Strawbridge, Deputy Director of Policy, Medicare Drug Rebate and Negotiations Group

Primary Manufacturer Attendees:

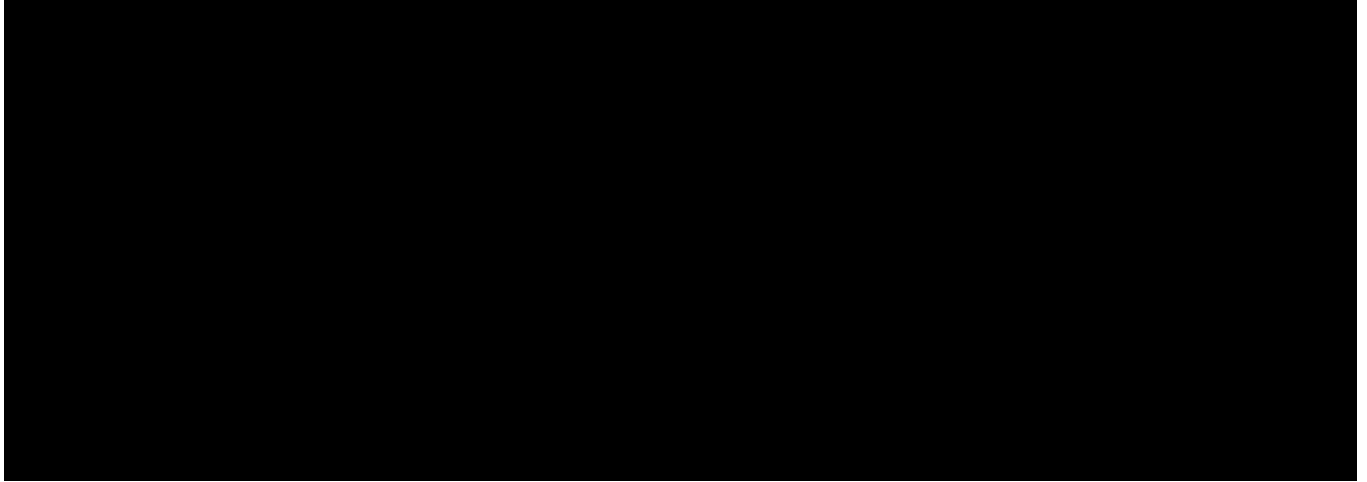
- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

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

- Introductions and meeting reminders
- Discussion of initial offer and questions from the Primary Manufacturer
- Discussion of counteroffer and questions from CMS
- Any other considerations that CMS and 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:





SUBJECT: Meeting Summary from Negotiation Meeting between the Centers for Medicare & Medicaid Services (CMS) and Pharmacyclics LLC regarding Imbruvica on May 31, 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. Pharmacyclics LLC (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Imbruvica (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 26, 2024, each party had the opportunity to request one additional negotiation meeting, resulting in a maximum of three meetings. The Primary Manufacturer requested a second 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 second negotiation meeting, which was held on May 31, 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. Joel McElvain, Representative from the Office of the General Counsel
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.

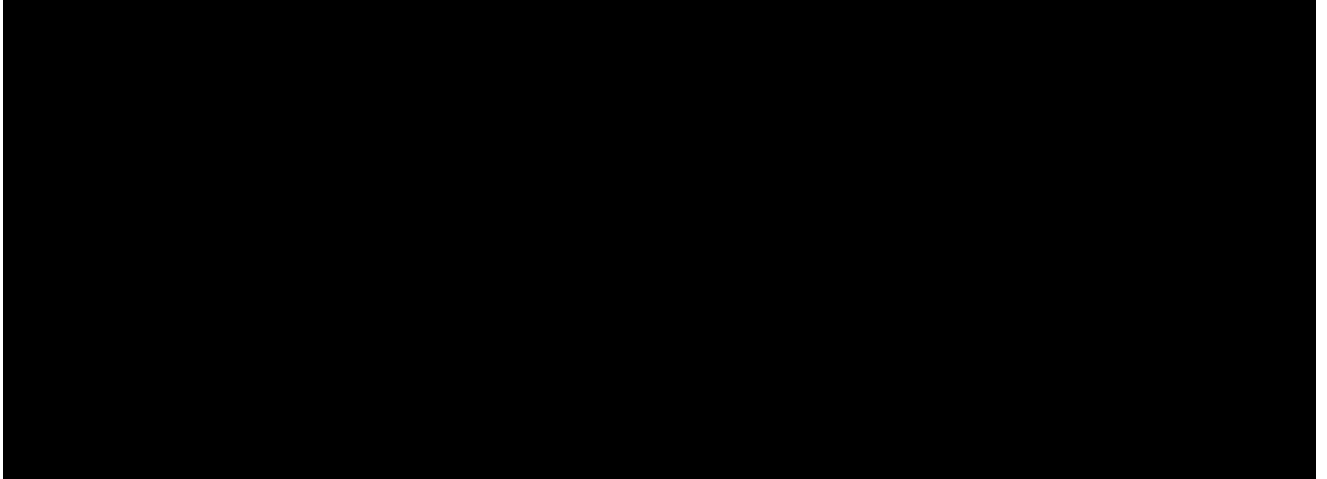
Topics: The discussion focused on topics outlined in the final agenda for the meeting, which was as follows:¹

- Introductions and meeting reminders
- Any additional information from the Primary Manufacturer on comparative adverse event evidence across BTKis (including head-to-head studies, economic adverse event burden, and real-world evidence on the management of cardiovascular adverse events)
- Unmet medical need re: cGVHD and oral suspension
- Commercial net price
- Therapeutic alternative selection
- FDA applications and approvals

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

- Patient perspective
- Therapeutic advance
- R&D and acquisition costs
- Patents and exclusivities
- Discussion of Primary Manufacturer's request to understand the pathway for voluntary termination
- 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 Pharmacyclics LLC regarding Imbruvica on June 27, 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. Pharmacyclics LLC (hereafter “the Primary Manufacturer”) chose to enter into an agreement to participate in the Negotiation Program for Imbruvica (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 the Primary Manufacturer and held on May 31, 2024, CMS had the opportunity to request one additional negotiation meeting, resulting in a maximum of three meetings. CMS requested a third 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 third negotiation meeting, which was held on June 27, 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. Joel McElvain, Representative from Office of the General Counsel
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:¹

- Introductions and meeting reminders
- Discuss overview of prior discussions and next steps after third meeting
- Revised offer/counteroffer price discussion
 1. Adjustment due to R&D recoupment and acquisition costs
 2. Adjustment due to patents, exclusivities, and FDA approvals
 3. New information informing comparative benefit since the May 31 meeting
- Any other considerations that CMS and the Primary Manufacturer would like to discuss

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

- Next steps

Offers/Counteroffers Exchanged:

