December 11, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-5528-IFC
Baltimore, MD 21244-8013

Re: Most Favored Nation (MFN) Model (CMS-5528-IFC)

Dear Administrator Verma:

Coherus BioSciences ("Coherus") submits these comments in response to the Centers for Medicare & Medicaid Services (CMS) *Most Favored Nation (MFN) Model* interim final rule with comment period (IFC), published in the *Federal Register* on November 27, 2020. The MFN Model has an effective date of November 27, 2020 and, as finalized, will be implemented January 1, 2021.

Coherus is the nation's only biotechnology company focused exclusively on developing, licensing and commercializing high-quality biosimilar products. The *Biologics Price Competition and Innovation Act* (BPCIA) included a pathway for biosimilars to be developed and approved in the U.S. with the intent to provide equally safe and effective versions of reference biologics to compete in the marketplace. Following the passage of the BPCIA, Coherus was established to realize the promise of biosimilars. Coherus is a U.S.-based company and now employs over 325 team members in the U.S., comprising all aspects of R&D, Product Development, Marketing and Sales, and other areas. Coherus is committed to high quality, not high cost, and we believe all Americans should have access to life-changing biologic therapies.

We developed our first – and only – marketed product, UDENYCA® (HCPCS code Q5111, Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg), a biosimilar to Neulasta® (HCPCS code J2505, Injection, pegfilgrastim, 6mg), in our labs in Camarillo, California. As CMS has identified in the IFC's Illustrative MFN Drug Payment Amounts,[1] the illustrative applicable average sales price (ASP) for UDENYCA® is less than 8 percent of the reference product's illustrative applicable ASP. Based on this information, for each use of our biosimilar instead of the reference product, CMS saves more than $3,930. We estimate that UDENYCA® has saved $1 billion for Medicare Part B since it became available in January 2019. In addition, the introduction of UDENYCA® has halted price increases for the reference product, reducing beneficiary cost-sharing and protecting the Medicare Trust Fund. Finally, please note that UDENYCA® is only sold in the U.S.

As a preliminary matter, we express our concern with how CMS has implemented this model. Since the MFN Model makes drastic changes to how Medicare Part B pays for drugs and biologics, there must be a robust notice and comment period so stakeholders can provide feedback and avoid situations such as those that uniquely impact Coherus. While we recognize CMS issued an Advance Notice of Proposed Rulemaking (ANPRM),[2] the finalized MFN Model is a significant departure from the originally contemplated model discussed in the ANPRM. For example, as released, the ANPRM described 27

[1] 85 FR at 76207-76212.
[2] 83 FR 54546.

included drugs and relied on an October 2018 Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) analysis that explicitly excluded biosimilars.[3]

Generally, our comments to the IFC describe our deep concerns with the expected impact of the MFN Model, specifically on biosimilars and UDENYCA®. Our comments focus on the following:

1. UDENYCA® should be excluded from the MFN Model as the U.S. is the most favored nation for this biosimilar.
2. Biosimilars, generally, should be excluded from the MFN Model.
3. The MFN Model methodology is clearly flawed.

For the reasons described below, **we request that CMS exclude UDENYCA® as an MFN Model drug and generally exclude biosimilars consistent with the ASPE analysis.**

1. UDENYCA Should be Excluded from the MFN Model

UDENYCA® is manufactured in and only available for use in the U.S. In other words, the U.S. is the MFN as the product is not available internationally. Including UDENYCA® in the MFN Model serves no purpose and does not support the goals of "end[ing] foreign freeloading" and "spur[ring] biomedical innovation."[4] On the contrary, the MFN Model disregards what UDENYCA® has achieved and will undermine the billions of dollars in actual and anticipated savings for American patients and the Medicare program.

We recognize CMS's concern that "Medicare pays substantially more than other countries for many of the highest-cost Medicare Part B drugs."[5] According to CMS, the MFN Model "aims to take a global approach to calculating Medicare Part B drug payment amounts, by testing a new payment methodology that takes into account the discounts that other countries enjoy."[6] However, these stated goals simply do not apply to UDENYCA®. No other country enjoys the significant savings associated with UDENYCA® and there is no "foreign freeloading" associated with this biosimilar.

In addition, including UDENYCA® in the MFN Model is especially damaging to Coherus, which is the only smaller manufacturer to have successfully developed and launched one of the 120 biosimilars in development in the U.S. In its October 2020 publication, IQVIA specifically stated, "[o]nly one product has been developed and launched by a smaller company, Coherus Biosciences, highlighting the likelihood that the complexities and costs of marketing biosimilars are likely filtering out smaller competitors."[7] Rather than spurring innovation, the MFN Model will have devastating effects for Coherus, which has overcome the complexities and costs to create significant savings for Medicare and patients. More specifically, the MFN Model will severely compromise our ability to continue to market UDENYCA® in the U.S., which will lead to access concerns and eliminate the future anticipated savings associated with this biosimilar that only the U.S. benefits from. In addition, the MFN Model will significantly curb our ability to continue development of additional biosimilars in our pipeline.

While we recognize that CMS has established the MFN Drug Payment Amount as the drug's ASP if international data is unavailable, as should be the case with UDENYCA® since it is not available

[3] Available at: https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf at 8 and 12.
[4] 85 FR at 76181.
[5] 85 FR at 76180.
[6] 85 FR at 76181.
[7] Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_=1607274138333 at 6.

internationally, we are concerned that CMS's methodology is flawed. As described below, CMS inexplicably assigns MFN Prices to UDENYCA® in a manner inconsistent with the required regulations.

In order to prevent these unintended consequences that would harm Coherus, curb innovation, and reduce savings to patients and the Medicare program by limiting access to UDENYCA®, we request you exclude this biosimilar from the MFN Model.

2. Biosimilars Should Be Excluded from the MFN Model

The goal of the MFN Model is to lower drug prices for Medicare beneficiaries by ensuring that the Medicare program pays no more for certain high-cost, physician-administered Part B drugs than the lowest price charged in other similar countries. Biosimilars already have been achieving lower prices in the U.S.

As a biosimilars manufacturer, Coherus is committed to ensuring patient access to high quality, not high cost, medicines. We have achieved this through the biosimilars pathway and steps this Administration has taken to support biosimilars. The BPCIA was passed to support innovation, including the development of biosimilars, to address drug pricing concerns through increased competition. As evidenced by UDENYCA®, the availability of biosimilars does in fact curb high drug prices through price competition and creates savings for the Medicare program by offering access to equivalent, but lower priced alternatives.

We direct CMS to the stated need for regulatory action and the Administration's drug pricing related activity leading to this IFC.[8] Notably, President Trump's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs ("Blueprint")[9] sought "to encourage innovation, while also promoting better price competition and addressing foreign freeloading" and "advance biosimilars and generics to boost price competition." Further, the Administration has taken concrete steps, for which we are thankful, to support biosimilars. For example, the Food and Drug Administration (FDA) launched a new program to educate doctors about biosimilars,[10] and CMS adopted a policy to assign a separate HCPCS code to each biosimilar to "encourage innovation needed to bring more products to the market."[11]

With respect to biosimilars, CMS states:

> We are not excluding biosimilar biological products from the MFN Model, however, given the relative lower annual Medicare Part B spending for HCPCS codes for separately payable biosimilar biological products through 2019, only one biosimilar biological product is included among the performance year 1 MFN Model Drug HCPCS Codes List.[12]

Unfortunately, the one biosimilar biological product included in the MFN Model is UDENYCA®. The limited inclusion of biosimilars in the MFN Model is not a valid justification for this policy. This is especially the case for a biosimilar like UDENYCA®, which already has unquestionably achieved the goals of the MFN Model by lowering prices through the use of price competition rather than the MFN Model's "top down" government-run approach of price fixing.

[8] 85 FR at 76249-76250.
[9] Available at: https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.
[10] Available at: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars.
[11] 82 FR at 53186.
[12] 85 FR at 76189.

Instead, CMS should exclude biosimilars for the same reasons the agency excludes generics. Although biosimilars are different from generic drugs, they serve the same purpose (increased price competition) and function (reduced drug spending) as generic drugs.

The MFN Model also undermines the biosimilar pathway and is counter to the benefits of biosimilars that the President, Congress, CMS, and FDA have so clearly described and supported over the years. The ultimate impact of the MFN Model on biosimilars is to prevent, not support innovation. The financial impact on Coherus will be severe, as we have focused solely on bringing enhanced value through biosimilar innovation. We urge CMS to reconsider its limited exclusions to the MFN Model such that they extend to biosimilars. This step will continue the Trump Administration's many efforts "to encourage the introduction and use of biosimilars"[13] to curb high drug costs and create savings for beneficiaries and the Medicare program.

CMS states repeatedly that there is "an unusually high degree of uncertainty"[14] with the MFN Model, but we are certain of the impact of this Model on UDENYCA® and Coherus. Subjecting UDENYCA® to the MFN Model will jeopardize its availability in the U.S., undoing the gains made with respect to Part B drug savings achieved as well as domestic production of biosimilars. We have relied on the statutorily established biosimilars pathway and the free market competition that has encouraged the innovation, development, and use of biosimilars. Introducing foreign pricing, regardless of those countries' "commitment to market-based economies"[15] undermines the existing efforts to control U.S. drug pricing and severely distorts the competitive domestic biologics market. In many respects, the availability of biosimilars abroad has demonstrated drug savings similar to what we have demonstrated with UDENYCA®. Including biosimilars, therefore, does nothing to increase competition and will only disrupt existing competitive forces and devastate the continued innovation and development of critically important biosimilars.

In addition, including biosimilars in the MFN Model ignores the longstanding policy that biosimilars are treated distinctly from their reference products. The Part B reimbursement system was specifically designed to account for the competitive benefits of biosimilars and their ability to reduce drug spending. ASPE's October 25, 2018 analysis comparing U.S. and international prices for the highest Part B drug spending specifically highlighted these concerns. ASPE stated:

> Our analysis does not include prices for biosimilars with the reference biologics, in part because the Medicare Part B reimbursement system treats biosimilars distinctly under current law and regulation… biosimilars are not included in the same HCPCS code as their reference biologic. As a result, this analysis did not include biosimilars in the U.S. or outside the U.S. in the analysis.[16]

The adverse impacts of the MFN Model are especially acute for biosimilars on transitional pass-through status under the OPPS. Currently, these biosimilars are reimbursed under the OPPS at ASP of the biosimilar plus six percent of the reference biological product. Transitional pass-through status is intended to ensure that Medicare beneficiaries have access to innovative treatments and is essential for ensuring new biosimilars can effectively compete against the reference product so that the corresponding savings can be realized. Including biosimilars on pass-through status in the MFN Model would eliminate the utility of this designation and, ultimately, beneficiary access to the benefits of innovation.

---

[13] 85 FR at 76189.
[14] 85 FR at 76237. See also *id.* at 76181, 76230, 76238, 76240, 76243, 76244, and 76246.
[15] 85 FR at 76199.
[16] Available at: https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf at 8 and 12.

3. CMS's MFN Model Methodology is Flawed

According to the MFN Model requirements, CMS will base the MFN Drug Payment Amount on the drug's ASP and MFN Price, using a blended amount for the first three years of the Model until the payment amount is 100 percent of the MFN Price.[17] In addition, CMS will provide a standardized per-dose add-on payment amount, estimated to be $148.73 for the first calendar quarter of performance year 1.[18] We have concerns with both elements of the payment methodology and believe there are serious flaws in the agency's implementation as finalized.

a. Application of MFN Price to Certain MFN Drugs

When identifying the MFN Price, the MFN Model regulation requires CMS to identify available international drug pricing information data sources "by aligning the MFN Model drug's HCPCS code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage formulations, as applicable."[19] CMS explains that it will identify the international data sources' standardized scientific name or nonproprietary name for that drug, and then use that naming to identify data for all products within that data source with an applicable formulation.[20]

On its face, the approach CMS describes is consistent with the September 13, 2020 Executive Order on Lowering Drug Prices by Putting America First,[21] which directed HHS to implement the MFN Model. When describing the purpose, the Executive Order states that "[i]t is unacceptable that Americans pay more for the exact same drugs." The finalized regulations' reliance on the HCPCS code long description should ensure that international data sources connect the exact same drugs' applicable ASP with MFN Prices. However, as evidenced in Table 6 of the IFC,[22] CMS is incorrectly applying its own rules when assigning MFN Prices.

The long description for UDENYCA® (HCPCS code Q5111) is different from that of Neulasta®'s (HCPCS code J2505).[23] Despite this significant difference, CMS has aligned both to the molecule pegfilgrastim.[24] This approach, again, is inconsistent with the MFN Model's finalized methodology and raises concerns that CMS will not follow its own finalized regulations when identifying MFN Prices based on the HCPCS code long description. Use of a molecule list and disregarding the long description results in incomprehensible outcomes such as the Illustrative MFN Prices in the IFC. For example, UDENYCA® is NOT available internationally, yet CMS has identified MFN Prices from Germany, Austria, and Australia – the same countries to which Neulasta®'s price is tied – which CMS assigned to UDENYCA®. This clearly shows that CMS is disregarding the fact that UDENYCA® and Neulasta® are separate and distinct biological products with different availability internationally, and again disregarding the fact that UDENYCA® is NOT available internationally. This error is extremely troubling given the significant adverse impact this Model will have on UDENYCA® specifically and biosimilars more broadly.

In addition, CMS specifically finalized that in the absence of international drug pricing information data sources, CMS "will establish the MFN Drug Payment Amount at the applicable ASP for the applicable

[17] 85 FR at 76200-76201.
[18] 85 FR at 76217.
[19] 85 FR at 76252. See also *id.* at 76253.
[20] 85 FR at 76201.
[21] Available at: https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/.
[22] 85 FR at 76207-76212.
[23] UDENYCA® (HCPCS code Q5111): Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg.
Neulasta® (HCPCS code J2505): Injection, pegfilgrastim, 6mg.
[24] Available at: https://innovation.cms.gov/media/document/supp-doc-cms-5228-ifc.

calendar quarter."[25] CMS explains that such cases may occur because the MFN Model drug is not approved for marketing in the included countries.[26] For example, CMS was unable to identify international price data for HCPCS codes J2507 and Q2043, and, therefore, the MFN Drug Payment Amounts for these drugs are the applicable ASPs.[27] If CMS continues to include biosimilars in the MFN Model, at a minimum, UDENYCA®'s MFN Drug Payment Amount should be its applicable ASP as required in CMS's final regulations.

b. Add-on Payment Methodology for Biosimilars

While we strongly believe CMS should exclude biosimilars from the MFN Model, if CMS maintains that they should be included, we strongly recommend that CMS revisit its add-on payment methodology such that the alternative add-on payment for biosimilars be calculated separately. As described above, Congress and the Administration have taken steps to ensure biosimilars receive an enhanced add-on payment so that providers are not disincentivized from using the more cost-effective biosimilar in lieu of the reference product. The fixed add-on payment that would apply to biosimilars under this model removes any incentive to administer the biosimilar product, meaning Part B spending will increase if physicians switch from the biosimilar to the much more expensive reference product.

Looking at UDENYCA® specifically, its ASP is considerably lower than that of its reference product, meaning the MFN Drug Payment Amount will also be considerably lower for the biosimilar. Absent the existing incentive in the form of an enhanced add-on payment for the biosimilar, physicians would be incentivized to administer the more expensive reference product. Thus, the MFN Model will result in physicians moving away from biosimilars and returning to more expensive reference products, increasing costs to Medicare and beneficiaries, while destroying the biosimilars pathway.

In addition, establishing a fixed add-on payment for both biosimilars and reference products on the MFN Model drug list will create an unfair competitive advantage for non-included biosimilars as they would receive the current enhanced add-on payment, but may never be included in the MFN Model. While the ASP for Neulasta® may decrease, its utilization may actually increase, meaning its total allowed charges would increase, while UDENYCA®'s total allowed charges are expected to decrease significantly. Because CMS will not remove drugs that no longer meet the criteria to be included, Coherus will continue to be penalized simply because it innovated. Further, it may be years before other biosimilars reach the threshold for inclusion, meaning CMS will continue to pay the enhanced add-on payment before they are capped at the fixed alternative add-on payment amount. All of these factors will have one, significant outcome: Medicare will spend more than it currently does without any benefit to beneficiaries.

[25] 85 FR at 76205.
[26] 85 FR at 76205.
[27] 85 FR at 76209 and 76212.

Conclusion

We reiterate our concerns and request CMS exclude UDENYCA® as an MFN Model drug. Please contact me at dsanders@coherus.com should you have any questions or if there is any additional information we can provide.

Sincerely,

/SIGNED/

David Sanders
Executive Director, Government Affairs and Policy