Memorandum (January 22, 2021)

To: Kristen Bernie, PhRMA

From: Mark Desmarais and Kevin Kirby

Subject: Analysis of Most Favored Nation Final Rule

On November 20, 2020 the Trump Administration released an interim final rule with comment period (IFC) that would set reimbursement for 50 Part B drugs and biologics based on international pricing data using so-called "Most Favored Nation" (MFN) prices. At the same time, the policy would replace the current 6% add-on for affected drugs with a flat dollar add-on per dose. This memorandum provides our analysis of the policy changing add-on payments for Part B drugs under the policy.[1]

Key Findings

- In the MFN rule, CMS presents a policy whereby providers of the selected Part B drugs will no longer be paid a 6% markup, but will now be paid a flat fee of $148.73.

- CMS reports that 70% of doses are "better off" when comparing the prior + 6% after applying sequester (thus 4.3%) to the purportedly sequestered flat add-on payment amount. However, we were able to replicate the CMS 70% figure only if the flat add-on amount used was not adjusted from the non-sequestered $148.73 add-on amount.[2]

- Even without adjusting the flat amount for sequestration, we project that 27 of the 50 drugs would see decreased reimbursement at their average dose.
    - The 70% figure is driven by the two most frequently delivered drugs subject to the policy, which both happen to be winners under the flat add-on amount.

- If we adjust the $148.73 to account for sequestration for the most appropriate comparison:
    - 37 of the 50 drugs would see decreased reimbursement at their average dose;
    - 55% of doses would see an increase; and

[1] Since its release, the implementation of the rule has been delayed by multiple courts.

[2] Sequestration of Medicare payments has been suspended legislatively during the COVID public health emergency, most recently until March 31, 2021. When sequestration of Medicare payments resumes, the flat add-on fee proposed under the rule would be affected.

- Again, the two most frequently dosed products make the comparison more positive. If these were excluded, we estimate only 38% of the remaining doses benefit from the policy.

Analysis

We took the list of 50 drugs covered by the MFN rule and calculated an average dose per administration using the drug cost statistics data released with the 2021 OPPS Final rule. These data report the total units and total "days" for each drug. We interpreted a "day" as a single administration for purposes of determining how often the flat fee would be paid. We then calculated and compared the 6% markup on Average Sales Price (ASP) times the average units per day as reported on this file. We compared these figures to ASP + $148.73 as the MFN pricing was not released at the time of the analysis.

In order to replicate the CMS claim that 70% of doses are better off, we had to assume that the "+ 6%" was sequestered while the flat add-on of $148.73 was not. In doing this, we arrived at 67% of the doses being better off under the MFN. If this is the comparison CMS made, it seems inadequate since we see no reason that the sequester would not apply to the flat fee as well. When the flat fee was adjusted for sequester and the analysis repeated, we found that only 55% of doses are better off with a flat fee.

In addition, the "doses" metric is an interesting metric to measure the overall impact of the switch to the flat fee. Two products (Lexiscan and Prolia) make up a substantial proportion of the overall doses. Both of these products also benefit from the switch to a flat add-on fee. If these two products were excluded and both fees were compared after sequester was applied, we find that only 38% of doses will be better off under the new flat fee payment policy.

Alternatively, one might consider examining how many of the products among the 50 covered by the MFN rule are better off rather that focusing on the doses as the impact metric. If both add-ons were adjusted for sequester, we find that 37 of the 50 products would be worse off under the flat-fee policy.

CMS projects that the flat add-on will result in increases for all but 9 of the 35 top specialties affected by the model—but those 9 specialties with losses include multiple oncology specialties whose impact will be much higher than some of the other specialties in the model. Since not all products are used by all specialties, the budget neutral construction of the flat add-on effectively transfers reimbursement from specialties including oncology to other specialties including ophthalmology.

Conclusion

CMS' impact analysis of the flat add-on payment policy appears to center on a metric which may not be the most appropriate way to measure the overall impact of the policy. Since "doses" represent different concepts for different products, the impact analysis obscures the fact that the flat add-on advantages lower price drugs which are frequently dosed rather than higher cost drugs which are dosed less frequently. This leads to nearly three-quarters of all products covered

by the policy being worse off than the current ASP + 6% reimbursement model, and also represents a reimbursement cut for specialties including oncology who only use the products disadvantaged by a switch to the flat add-on fee.