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To: Centers for Medicare and Medicaid Services
Submitted electronically via: regulations.gov

From: Shannon Schuster
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Date: December 3, 2019

Re: *CY 2021 Plan Benefit Package Software and Formulary Submission*

Attached are comments regarding the CY 2021 Plan Benefit Package Software and Formulary Submission.

CY 2021 Plan Benefit Package Software and Formulary Submission

Comments Submitted by
UnitedHealthcare
12/3/19

UnitedHealthcare (UHC) appreciates the opportunity to provide input to CMS regarding the CY 2021 Plan Benefit Package Software and Formulary Submission.

Plan Benefit Package (PBP) Software
Section A
Group Retiree Plans

Service Areas appear in Section A for individual MA/MAPD plans. However, in 2018, CMS removed "Service Area" from Section A of Group Retiree (800-series) plan PBPs. We respectfully request that CMS add "Service Area" back to Section A for Group Retiree (800-series) plans. This would help MA plans more easily confirm the accuracy and consistency between what appears in the PBP and the MA plans' internal data.

Section B
#7j Additional Telehealth Services – Base 1

This section requires MA plans to select each Medicare-covered benefit categories for which Additional Telehealth will be available. We recommend CMS remove this requirement as it hinders innovation and experimentation. With this level of detail in the PBP filing, Plans are restricted to only the filed telehealth features and cannot pay provider groups when they add additional provider types to their local telehealth services. This filing requirement also discourages testing to determine if telehealth can adequately support specific services. In light of the Administration's strong support of telehealth services, eliminating this requirement for plans to select the specific benefit categories that will have additional telehealth support would help promote the use and expansion of additional telehealth services.

Section C
Number of Out-of-Network Groups

The current limit on the number of out-of-network groups in Section C has negatively impacted UHC's ability to enter intended benefits in the cost sharing fields. When we reach the limit, we must file benefits in out-of-network groups that do not align with their intended cost share. We then add a note to explain which cost share is applicable to each benefit. UHC requests that CMS increase the limit of out-of-network groups in the PBP software or eliminate the limit in the PBP software altogether. This would allow out-of-network plan benefits to be more accurately captured in the filing, reduce the number of filed notes, and provide better data for members in Medicare Plan Finder and the Medicare & You Handbook.

General
PBP Data Reports

As we have noted during past comment opportunities, the "Export to PDF" option has been removed from the PBP software. To obtain a data report in this format, one must now export to Excel, open the Excel file, and then convert to PDF. We believe that these extra steps can add a significant amount of

time to the process. UHC respectfully requests that CMS add the "Export to PDF" functionality back into the PBP software.

Year-Over-Year Tracking

In order to help organizations track Year-Over-Year (YOY) benefit changes during PBP entry, it would be helpful if CMS were to implement functionality in the PBP software such that when an organization changes a benefit in the PBP, that PBP field changes to a different color so as to clearly delineate the change. We recommend that CMS introduce this PBP software functionality.

Planning, Creation and Testing

UHC would like to be involved in any potential changes to bid submission and offers our assistance in designing, implementing and testing any new functionality. We use the current CMS process and tools for our internal readiness every year. Thus, potential changes in the PBP software or overall bid submission process would impact our planning. The ability to understand and implement any changes timely will be critical to serving our members and meeting CMS' timelines for 2021 bid submission.

UHC respectfully requests to collaborate with CMS in its planning, creation and testing of any new PBP software and bid submission functionality. UHC will be able to provide valuable insight as to impacts of CMS' PBP and bid functionality changes to MA Plans and Part D Sponsors. We would like to offer an extensive partnership with CMS to help make this potential change easier for industry stakeholders.

Formulary Submission

September Update Alignment with Member Materials

CMS should allow pricing files to be accepted prior to the Annual Election Period in order to allow for September submission updates. For example, the drug Lyrica was not added to Formulary Reference File (FRF) until September, so in October, it appeared on the Medicare Plan Finder as "noncovered", even though UHC submitted it as "covered". UHC recommends the acceptance of earlier price file submissions in order to increase transparency with members.

QL-type 3

UHC recommends CMS update HPMS submission fields to add acceptance/validation for a QL type 3 to allow for a "days over days" allowance. For example, Zolpidem 10mg tablets quantity limit type 3 of "90 days per 365 days". Beers Criteria recommends that the elderly not use High Risk Medication (HRM) sedative hypnotics, such as Zolpidem, for more than 90 days per year; however, there is no way to file a QL for "90 days per 365 days" to address these safety concerns. Updating the quantity limit fields would allow for HRM sedative hypnotics to be set up according to Beers Criteria recommendations and allow for any future drugs with this unique requirement.

QL-type 4

UHC recommends that CMS also update HPMS submission fields to add acceptance/validation for a QL type 4 to indicate a "once per lifetime" allowance. For example, Zostavax, is a drug/vaccine that is only to be administered once per lifetime. UHC requests that CMS allow plans to include a specific notation in Medicare Plan Finder and other member materials indicating a "once per lifetime" allowance instead of requiring plans to file Prior Authorization for these types of drugs. This update would increase

transparency for members, increase plan efficiency, and align pharmacy billing practices to mitigate fraud, waste and abuse.

Increased Standardization and Transparency on the FRF

UHC recommends that CMS provide a flag on the FRF to indicate 1) limited access and 2) drug category/class. UHC also recommends that CMS disclose, as part of the 2021 Call Letter, the clinical guidelines used in the formulary stage review process. Clinical guidelines would help plans better align with CMS' expectations during stage reviews, thereby decreasing discrepancies and increasing the accuracy of the bids. UHC provides additional detail on each of these recommendations, as follows:

Limited Access

UHC recommends CMS provide the limited access flags in the FRF consistently, applying to all plans equally, to decrease member confusion. In the Health Plan Management Formulary Submission Module and Reports Technical Manual (May 2019), drugs are flagged as limited access if access to the drug is limited to certain pharmacies. During the July 2019 Monthly Formulary Submission, erlotinib (generic Tarceva) received a line level rejection because CMS did not agree with UHC's flagging of this drug as limited access. CMS had previously approved brand Tarceva as limited access. This created a difference between the limited access status of the brand and the generic. UHC requests that CMS be consistent with the limited access flag, and standardize its application to all plan sponsors equally through the FRF.

Drug Category/Class

UHC recommends CMS provide drug categories and classes in the FRF used in the CMS formulary review process. This additional guidance would help both the plan and CMS ensure compliance, and decrease time and resources in formulary review. In addition, providing the categories and classes of FRF drugs would increase transparency for beneficiaries. In Chapter 6 of the Prescription Drug Benefit Manual (PDBM), Section 30.2.1, CMS states that plans may use an existing classification system or create their own and there must be at least two drugs per category or class. Currently, if a plan is using United States Pharmacopeia (USP) or their own classification system they have no visibility into the CMS categories and classes being used to review plan formularies, especially for the two drugs per category or class requirement. This was evident in the annual 2020 Stage 2 review of formularies, where UHC had two drugs per category or class, but not in the same category or class CMS used to review the formulary. UHC requests that CMS standardize the category or class in the FRF, and apply to all plans equally. By standardizing categories and classes across plans, it would make it easier for beneficiaries to compare different plans' drug coverage in member materials.

In addition, standardizing category or class in the FRF would eliminate other formulary stage review discrepancies experienced by plans, including the Tier Outlier Review. In Chapter 6 of the PDBM, Section 30.2.4, CMS states "[i]f not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must ensure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment." In the recent 2020 Stage 2 review of formularies, UHC followed the above Chapter 6 guidance, but was called out for a tier outlier review based upon CMS not using the same category or class designations in their review. To be specific, CMS identified Mitoxantrone as a "Multiple Sclerosis Agents" and UHC identified it as "Antineoplastic, Other". UHC recommends standardizing the categories and classes used in the formulary review process to provide clarity to plan sponsors and improve the efficiency of the review. This would reduce plan confusion as to which drugs meet CMS requirements. UHC believes that not only would it would improve the Tier Outlier Review process, but it would increase bid accuracy if CMS

specified any tiering requirements outside of the category and classification system prior to stage 0 formulary submission.

For all of these stated reasons, UHC recommends that CMS: 1) standardize drug categories and classes on the FRF, 2) specify any tiering requirements outside of the drug categories and classes prior to stage 0 formulary submission and 3)remove any drugs from the FRF that do not meet CMS requirements.

Removal of the Annual Submission of a Plan's Opioid Strategy

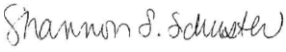
CMS is proposing to remove the request to upload responses for what comprehensive strategies an organization is using to combat the opioid crisis. UHC appreciates the removal of this requirement.

Adjustments to the Bid Submission Tool to Support Strategies Addressing Opioid Overutilization

UHC submitted the following request during last year's comment opportunity, but believes it is crucial to aid in addressing opioid overutilization. For that reason, UHC again requests that CMS adjust the bid submission tool to permit plans to file Part D benefits that both exclude opioids from mail order benefits, and limit opioid benefits to a 30-day supply only for retail benefits. UHC would expect that formulary materials would display these limitations as well. Currently, a Part D sponsor can limit opioids from an extended day supply, but there is no option to only provide opioids at retail.

If you have any questions on these comments, please feel free to contact me at 920-661-6217.

Respectfully,



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