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

From: Shannon Schuster
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Re: *CY 2020 Plan Benefit Package Software and Formulary Submission*

Attached are comments regarding the CY 2020 Plan Benefit Package Software and Formulary Submission.

CY 2020 Plan Benefit Package Software and Formulary Submission

Comments Submitted by UnitedHealthcare 11/30/18

UnitedHealthcare (United) appreciates the opportunity to provide input to CMS regarding the Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP).

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

Inpatient Hospital-Acute Benefit Period (1a, Base 12)

In this section, the question "What is your Inpatient Hospital-Acute benefit period?" is disabled when the benefit is filed as \$0 per stay or \$0 days 1 - X. Further, if an MA plan files additional days with a cost share, the question is still disabled. United requests that this question be enabled for all scenarios for CY 2020 to allow MA plans to capture consistent data across all benefit set-ups.

Inpatient Hospital Psychiatric Benefit Period (1b, Base 12)

In this section, the question "What is your Inpatient Hospital Psychiatric benefit period?" is disabled when the benefit is filed as \$0 per stay or \$0 days 1 - X. Further, if an MA plan files additional days with a cost share, the question is still disabled. United requests that this question be enabled for all scenarios for CY 2020 to allow MA plans to capture consistent data across all benefit set-ups.

Skilled Nursing Facility Benefit Period (2, Base 10)

In this section, the question "What is your SNF benefit period?" is disabled when the benefit is filed as \$0 per stay or \$0 days 1 - X. Further, if an MA plan files additional days with a cost share, the question is still disabled. United requests CMS enable this question for all scenarios for CY 2020 to allow MA plans to capture consistent data across all benefit set-ups.

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 United'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. United 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

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number of filed notes, and provide better data for members in Medicare Plan Finder and the Medicare & You Handbook.

Sections B & C

Remote Access Technologies

In Section B of the PBP software, the cost sharing fields are separate for Remote Access Technologies-Nursing Hotline and Remote Access Technologies-Web/Phone-based Technologies. However, in Section C, there is currently only one field for 14c7 Remote Access Technologies. Because there is only one field for Remote Access Technologies in the Section C Picklists (14c7), MAOs are required to file a range and a note for plans that have different cost sharing for Nursing Hotline and Web/Phone-based Technologies. We recommend that CMS create the same separate fields for Section C cost-sharing as appear in Section B, so that there is consistency in how the Remote Access Technologies categories appear in Sections B & C and to allow the cost-sharing in Section C to be precisely described.

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

Training Version of the Software

United recommends that CMS provide a generic training version of the final PBP software for use by MA plans for development and internal review purposes. Similar to the beta PBP software that has been released, we ask that CMS provide a training version of the final PBP software that does not require a "real" user identification. This would be for local use only with samples of all plan types and use of "virtual" contracts similar to the beta 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

United 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's timelines for 2020 bid submission.

United respectfully requests to collaborate with CMS in its planning, creation and testing of any new PBP software and bid submission functionality. United will be able to provide valuable insight as to impacts

of CMS's 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

Indication-Based Formulary Design

File Record Layout

As part of the 2020 Formulary Submission, Indication-Based Coverage will have additional fields added to the HPMS submission. The August 29, 2018 HPMS memo "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020", included the Record Layout for 2020, which included two fields: "RxCUI" and "Indication Code". The HPMS memo states that the Indication Code will be based on a standardized terminology system. United recognizes that the system to be used is the National Institute of Health's (NIH's) Medical Subject Headings (MeSH) as indicated by the example in the Record Layout. If MeSH is not used, we ask CMS to clarify which system will be used.

Indication Codes

On the Formulary Reference File, there are drugs with multiple indications. We ask CMS for clarification whether there be more than one indication code per RxCUI. For example, RxCUI 727705 (Humira 40mg Kit) would have an indication code of rheumatoid arthritis, Crohn's disease and psoriasis, which would indicate that Humira is only coverable for those indications (and not for all other indications). United recommends that CMS advocate to the National Council for Prescription Drug Programs (NCPDP) to include ICD-10 codes on pharmacy point of sale claims, which would help MA plans identify diagnoses that could be used for indication-based formulary design. This would help with immediate adjudication of claims for members under this formulary design.

Bid Submission Process

In the August 29, 2018 HPMS memo "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020", formulary submission changes were addressed, but there was no mention of changes to the bid submission process. United recommends that CMS update the bid submission tool so that MA plans may indicate whether or not they will utilize an indication-based formulary.

Transition Policy

It is not clear whether transition benefit guidance will change with the new formulary design. There may be a year-over-year negative change at a very specific member level based on the member's indication for the drug, but the actual utilization management (such as prior authorization (PA)) submitted will remain the same. It will be very challenging to operationalize transition benefit policy based on singular drug indications. United recommends that the existing transition benefit policy remain as it is currently, regardless of the content of the PA criteria. For example, in 2019 Humira is on tier 5 with PA and all indications are coverable. In 2020, Humira is still tier 5 with PA, but the PA criteria would state the drug is only formulary for Rheumatoid Arthritis, but non formulary for Crohn's Disease. In this example, United's interpretation is that there is no year over year change, so it would not be transition eligible due to a negative formulary change in 2020.

Formulary Exceptions and Tier Cost Exceptions for Specific Indications

If a beneficiary requests a formulary exception to use Humira for ulcerative colitis, United's understanding is that the beneficiary would be required to try and fail all of our formulary alternatives, UnitedHealth Group/UnitedHealthcare

but it is not clear whether the claim should pay at the filed tier or the exception tier. If a formulary exception for a specific indication is approved at the filed tier, the purpose of preferred products in an indication-based formulary is defeated; therefore, United recommends that these exception requests pay at the exception tier, with the understanding that Part D sponsors have an appropriate timeframe for implementation. Using the Humira example, in 2020 Humira is tier 5 with PA, with PA criteria that states the drug is formulary for Rheumatoid Arthritis, but non formulary for Crohn's Disease. In this example, United's recommendation is that if a member receives a non-formulary exception for the Crohn's Disease indication, the claim would pay at the exception tier and not at tier 5.

Formulary Materials

The recent guidance provides information on how to notify beneficiaries of the indication-based formulary management change in the Annual Notice of Change and Evidence of Coverage and directs beneficiaries and providers to the posted PA criteria for specific indication coverage. United is concerned about this approach, as the PA criteria are complex and can be difficult for beneficiaries to comprehend. Formulary materials are not going to change, but the Indication-Based criteria will require members to try and fail alternatives based upon indication. Due to confusion that may result as part of this new formulary design and Part D sponsors and beneficiaries adjusting to it, United recommends that Complaint Tracking Modules (CTM) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) results related to this new formulary design not count against a Part D sponsor's Star Rating measures for at least the first year of implementation.

General

United also requests CMS to adjust the bid submission tool to permit the following functions that align with CMS' recommendations on strategies to address opioid overutilization. In recent years, CMS has made substantial programmatic changes to address opioid overutilization and abuse. Additionally, recent legislation such as the SUPPORT Act, aimed at combating the opioid crisis, passed several fraud and deceptive practice prohibitions. In that same vein, United proposes an additional change to permit Part D sponsors to limit opioids to face-to-face fills only. United recommends CMS adjust the bid submission tool to allow 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. United 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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