Plan Benefit Package (PBP) Software

Comment:

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.

Response: This was removed to address improving bid processing efficiency and design. The service area is reflected in various reports and extracts in HPMS.

Comment:

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.

Response: This is a defect, and will be fixed with the release of the CY2020 PBP.

Comment:

Section B
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.

Response: This is a defect, and will be fixed with the release of the CY2020 PBP.

Comment:

Section B
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.

Response: This is a defect, and will be fixed with the release of the CY2020 PBP.

Comment:

Section B: "B15 Medicare Part B Rx Drugs."
CMS is proposing to revise Section B-15 of the PBP, "Medicare Part B Rx Drugs," to include a new Step Therapy (ST) question for MA plans offering a drug benefit. In addition, CMS indicates that if the answer to the ST question is "yes, a note will be required."

Although the agency has noted on the relevant PBP data entry screen that the screen "will be updated" to include the ST question, the language for the newly proposed question has not yet been incorporated. In addition, CMS has not yet described the specific information that will be required in the "note" that must be populated if the plan answers "yes" to the new question, and it is unclear whether utilizing a notes field will be sufficient to capture the detail needed to ensure the benefit is described appropriately. To ensure clarity and to provide an opportunity for plans to review and comment on these key details (i.e., the new question and related instructions for populating the notes field), we recommend that CMS include these details when the proposed information collection is released for further comment during the subsequent 30-day PRA opportunity.

Response: This will be included in the 30-day PRA package.

Comment:

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

Response: CMS will consider this comment for the future. CMS notes that up to 15 categories can be created for out-of-network (OON) groupings, and a minimum-maximum range is provided to fully collect the cost sharing for OON benefits.

Comment:

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.

Response: CMS will consider this for the future development.

Comments:

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.

Response: There are multiple ways for a user to export this data from the PBP, and CMS does not want to limit users to just exporting to a PDF. Users can export the report in Excel and save the PBP reports in whatever format is preferred. CMS will consider this for the future development.

Comments:

General

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.

Response: This comment is outside the purview of this PRA package. CMS will explore the possibility of posting a training version of the CY2020 PBP software.

Comment:

General

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.

Response: CMS will consider this comment for the future development. CMS also notes that the "Change Notification Report – PBP" outlines changes between different versions of the submitted bid.

Comment:

General

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.

Response: This comment is outside the purview of this PRA package. CMS provides a PBP testing period for the industry in January to solicit comments and feedback on the PBP design. CMS will consider this comment for the future development process.

Comment:

A number of changes were noted for the PBP. Among those changes are a screen to indicate new changes to address the details of a plan's opioid overuse monitoring, screens on telehealth and $0 vaccines, and details on indication-based formulary design. However, while CMS is proposing to collect general information on Part B step therapy (whether or not a plan intends to implement such therapy) via a notes field in PBP Section B15 ("Medicare Part B Rx Drugs"), it does not appear that the detail on this vital benefit will be collected by CMS. When CMS does not collect the information necessary to describe the benefits within a plan, then potential MA members are not aware of plan benefits prior to enrollment. As a result, we believe that the BPT and PBP should be modified for 2020 to track changes in the allocation of cost sharing to reflect the imposition of Part B step therapy. That is, if MA plans impose Part B step therapy, then there should be differences in cost sharing under Part B as opposed to Part D. Maximum out of pocket (MOOP) estimates would change as well. In addition, while the PBP collects information on whether or not an MA plan is implementing this change, there is no detail collected on this utilization management practice. Without collecting this information, CMS cannot provide details to prospective enrollees about the types of UM in Part B that a plan is considering. BCBSA encourages CMS to reconsider this oversight and begin to collect the information necessary to keep potential MA members educated about the UM practices in a plan. At a minimum, plans would need to fully

understand the type of information that will be required in the notes field under PBP Section B15 to support the new Part B step therapy question CMS is proposing to add.

With respect to the proposed changes to the upload document CMS uses to collect the details of a plan's opioid strategy (i.e., the "Opioid Strategy Layout"), we recommend that the agency release the final version of the layout as quickly as possible and well in advance of the upload deadline to ensure plan sponsors are afforded sufficient time to prepare submissions that are responsive to the full range of topics and questions on which CMS is seeking feedback.

Response: Opioid strategy will be part of the 30-day PRA package.

Formulary

Comment:

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.

Response: CMS appreciates this comment and intends to use Medical Subject Headings (MeSH) CUIs as the code for diseases/indications, although further sub-classification may be necessary for some indications.

Comment:

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.

Response: CMS appreciates this comment and clarifies that multiple indication codes can be submitted per RxCUI. Each unique RxCUI-indication code combination will need to be submitted to reflect which indications are covered by your organization. We appreciate the concern raised by this

sponsor regarding the ICD-10 codes on the point-of-sale claims, however, this comment is beyond the scope of this PRA submission. CMS will consider your comment in future policy.

Comment:

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.

Response: Thank you for your comment. This update will be incorporated into the Plan Benefit Package (PBP) software for CY 2020.

Comment:

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.

Response: CMS appreciates this comment, but this comment is beyond the scope of this PRA submission. Operational details regarding Indication Based Coverage will be forthcoming. CMS will consider your comment in future policy.

Comment:

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, 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.

Response: CMS appreciates this comment, but this comment is beyond the scope of this PRA submission. Operational details regarding Indication Based Coverage will be forthcoming. CMS will consider your comment in future policy.

Comment:

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.

Response: CMS appreciates this comment, but this comment is beyond the scope of this PRA submission. CMS will consider your comment in future policy.

Comment:

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.

Response: Thank you for your comment. Current policy allows a sponsor to limit availability via mail-order pharmacies to a subset of formulary drugs. Please refer to Chapter 5 of the Prescription Drug Benefit Manual, Section 50.2 Mail-Order Pharmacy Access. Opioid services are only being collected in Section B, not Section Rx.

Comment:

Opioid Strategy Upload. As part of the CY 2020 formulary submission process, CMS is again proposing to collect an upload of responses from Part D plan sponsors, via the "Opioid Strategy Layout," detailing the comprehensive strategies an organization uses to combat the opioid crisis. CMS indicates that the agency may utilize information submitted by plans "to assist in the modification of existing Part D policy and/or development of new policy" in this area. In addition, CMS notes that the agency may potentially synthesize the data collected and use the data to publish "best practices," although any information publicly disclosed will not be attributed to a specific organization.

- Final upload requirements and layout. We recommend that CMS release the final version of the "Opioid Strategy Layout" as quickly as possible and well in advance of the upload deadline to ensure sponsors are afforded sufficient time to prepare submissions that are sufficiently responsive to any new and/or revised topics and questions.

- Future Part D policy development. As noted above, CMS intends to utilize information received from the proposed opioid strategy upload to help inform potential future policy changes and/or development of new policy related to combatting the opioid crisis under the Part D program. We believe it will be important for Part D plan sponsors to have an opportunity to review and comment on any proposed policy changes before they are finalized, as these steps will allow plans to provide CMS with feedback informed by practical experience and will permit the agency to consider potential operational challenges before processes and guidance become final. As a result, we recommend that CMS provide a meaningful opportunity for comment on any future program changes related to combatting the opioid crisis under Part D, before any such changes are finalized.

Response: Thank you for your comment. CMS will post the Opioid Strategy layout within HPMS once finalized. CMS intends to review these submissions to help inform potential future policy or guidance. Before finalizing any new policy, CMS will communicate those changes through either the Call Letter or proposed rulemaking, whichever is more applicable, both of which are subject to stakeholder comment.