DEPARTMENT OF HEALTH & HUMAN SERVICES

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 119**

For

Participating Drug Manufacturers

This release provides frequently asked questions (FAQs) regarding line extension drugs. On December 31, 2020, the Centers for Medicare & Medicaid Services (CMS) published a final rule, *Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482-F)*, that included definitions of "line extension" and "new formulation."[1]

Pursuant to the regulatory definition at 42 C.F.R. § 447.502, a line extension is a new formulation of the drug but does not include an abuse deterrent formulation of the drug. The regulation defines a new formulation as a change to the drug that includes but is not limited to an extended-release formulation or other change in release mechanism, a change in dosage form, strength, route of administration or ingredients. Manufacturers must apply these definitions to determine whether a drug is a line extension.

Since the publication of the final rule, CMS has received several questions related to line extensions. This FAQ document is designed to provide additional information and clarity regarding line extensions, the Medicaid Drug Program (MDP) system, reporting requirements, and dates.

I. Field and Term Descriptions

Q1: What are the fields used in MDP related to line extension drugs?

A1: There are four data fields in the MDP system that relate to line extensions:

1. **Line Extension Drug Indicator ("LEDI") field-** a product data field that identifies a national drug code (NDC) as a line extension drug.
2. **Initial Drug Available for Line Extension ("ID Available for LE") field-** a quarterly pricing data field that identifies whether there is an initial drug to be used in the

[1] https://www.govinfo.gov/content/pkg/FR-2020-12-31/pdf/2020-28567.pdf

calculation of the alternative unit rebate amount (URA) for the line extension for the applicable quarter.

3. **Initial Drug field -** a quarterly pricing data field that identifies the NDC of the drug with the highest additional rebate ratio (calculated as a percentage of Average Manufacturer Price (AMP)).
4. **Initial Drug Indicator field** – a system-generated product data field that denotes whether the NDC has ever been reported by a labeler of a line extension as an initial drug for one or more quarters.

Q2: Why is it significant that some fields are identified as product data and others are pricing data?

A2: Product data represents an element that generally does not change from quarter to quarter because it is an attribute associated with the drug. If a drug is a line extension because it satisfies the definition, that attribute does not change from quarter to quarter beginning with the first quarter of 2022. However, it is important to emphasize that simply identifying a drug as a line extension does not automatically mean that the alternative URA calculation applies each quarter. For example, if there is no longer an initial drug that is active in the Medicaid Drug Rebate Program (MDRP) during the quarter (i.e., an NDC, active in the quarter, that is produced or distributed by a manufacturer with an active Medicaid National Drug Rebate Agreement (NDRA)), the line extension definition still applies to the line extension, but there will be no initial drug to report, and therefore no alternative URA calculation is performed.

Quarterly pricing data needs to be evaluated every quarter, based on activity that occurred during the quarter and may change from quarter to quarter. As average manufacturer price (AMP) and the Consumer Price Index for All Urban Customers (CPI-U), among other pricing data, are not static numbers, the quarterly pricing data must be reevaluated each quarter to determine the effect of changes in AMP and CPI-U on the quarterly pricing. Similarly, even though the "Line Extension" and the "Initial Drug" fields are populated with data that are not monetary figures, they nonetheless represent pricing data that must be evaluated each quarter. Further, as discussed in more detail later, the NDC that qualifies as the initial drug can change from quarter to quarter.

The "Initial Drug" field is also considered pricing data because it is used to calculate the URA for the line extension; manufacturers must use the additional rebate amount and the AMP value for the initial drug in the calculation. The additional rebate amount and the AMP value are pricing data that can change from quarter to quarter.

Q3: What is the "Line Extension Drug Indicator (LEDI)" field used for?

A3: If a drug satisfies the definition of a line extension, the "LEDI" field should be "Yes". This field is part of the product data for an NDC and applies to all package sizes (NDC-11s) under an NDC-9. It is generally reported one time and, like most other product data, will generally not change for the life of the NDC. The identification of a drug as a line extension does not depend on whether there is an initial drug available. For example, if all potential initial drugs for a line extension are terminated, or otherwise not active in the MDP system, the status of a drug as a

line extension does not change. Rather, in such cases, when pricing data is reported for such a line extension, the manufacturer should report that there is no initial drug.

Q4: There is a checkbox on the product screen that identifies an NDC as an initial drug, but a manufacturer is unable to check the box. How does the manufacturer identify that NDC as an initial drug?

A4: An "Initial Drug Indicator" field appears on the *Manage Products* screen in MDP. This field is system-generated, meaning that MDP system users are not able to modify it. The "Initial Drug Indicator" denotes whether an NDC has ever been reported by a labeler of a line extension drug as an initial drug for one or more quarters. When this indicator reflects that a drug has been reported as an initial drug, the labeler of that drug should be aware that product data changes or pricing data changes to the drug may impact the quarterly reporting of their own or another labeler's line extension drug(s). Consequently, the labeler of the initial drug should be sure to notify the labeler of the line extension drug of any product data changes or pricing data changes to the drug. The labeler of the line extension drug can, in turn, determine whether it is appropriate to continue reporting the product as an initial drug for its line extension drug or if the initial drug reported for a quarter needs to be changed. If a drug is reported as an initial drug and then later becomes ineligible for initial drug consideration due to one or more product data changes, this MDP system indicator continues to reflect that the drug was reported as an initial drug, even if it has not been reported as such for any other line extension drug.

Q5: What are terms used to describe the URA calculation and what do they mean?

A5: The following terms relate to the URA calculation:

1. **Basic URA -** For single source drugs and innovator multiple source drugs, the basic URA is the greater of:
    a. AMP minus the Best Price (BP); or
    b. 23.1% of AMP.[2]
2. **Additional URA -** An additional rebate, added to the Basic URA, if the AMP of the drug increased at a rate greater than the rate of inflation as measured using the CPI-U.
3. **Standard URA -** The URA calculated by adding the Basic URA plus any Additional URA.
4. **Alternative URA -** The URA calculated for drugs identified as line extensions using data from the identified initial drug.[3] *For a line extension, the URA for a quarter is the greater of the Standard URA or the Alternative URA.*[4]
5. **Additional rebate (calculated as a percentage of AMP) -** For a quarter, the amount of the additional URA is divided by the AMP. For example, if the quarterly AMP for a drug

[2] 17.1% for drugs identified as clotting factors or drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications.
[3] Unit Rebate Amount (URA) Calculation for Line Extension Drugs with example (medicaid.gov)
[4] The URA for a quarter is currently limited to 100% of AMP. As a result of the American Rescue Plan Act of 2021, there will be no cap on the maximum rebate as of January 1, 2024.

is $80.00 and the additional URA calculation yielded an additional URA amount of $10.00, then 10 would be divided by 80, which equals 0.125 or 12.5%. Thus, the additional rebate (calculated as a percentage of AMP) in this example is 12.5%.

II. Identifying a Line Extension

Q6: Will CMS help a manufacturer identify if its drug is a line extension?

A6: CMS continues to advise manufacturers, consistent with Manufacturer Release No. 78, dated June 26, 2007, that in the absence of specific guidance in the applicable federal laws and regulations, a manufacturer may make "reasonable assumptions" when reporting data to CMS. Those assumptions must be consistent with the requirements of the Medicaid statute (and any other applicable federal statute), federal regulations, the NDRA, and any other relevant guidance issued by CMS. Further, the manufacturer must maintain a record (written or electronic) explaining these assumptions in accordance with the recordkeeping requirements in 42 C.F.R. § 447.510(f).

Manufacturers should not submit their assumptions to CMS as CMS will not review or comment on a manufacturer's assumptions. If submitted, neither the receipt nor any subsequent inaction by CMS constitutes acquiescence by CMS to the submitted assumptions.

Q7: Can a drug that satisfies the definition of line extension be identified as a line extension even if there is no initial drug that can be reported for that drug (e.g., the initial drug is marketed by an unrelated manufacturer, or the initial drug is not active in the MDP system)?

A7: Yes, if a drug satisfies the definition of a line extension, it should be reported as a line extension (i.e., the "LEDI" field should be "Yes.") The absence of an initial drug during one or more quarters does not change the characteristic of a drug that makes it a line extension. The drug remains a line extension throughout its history.

The initial drug should be reported in any quarter for which it can be reported. Although there may not be an initial drug identified to report for a quarter at the time pricing is reported for that quarter, certain changes to potential initial drugs may qualify a drug to be reported as the initial drug after those changes are made. For example, in the case where a drug is reported as an initial drug, is then terminated, and then subsequently reactivated, the quarterly price reporting will indicate some quarters for which there was an initial drug reported, then some quarters for which there is no initial drug reported when the drug is terminated, and then an initial drug reported in the following quarters when the drug is reactivated. The alternative URA calculation and comparison to the standard URA calculation is required in quarters when there is an initial drug that can be reported for that quarter.

Q8: Can the first drug marketed in a family of drugs be a line extension?

A8: No, per 42 CFR § 447.502, new formulation means, "for a drug, a change to the drug, including, but not limited to: an extended-release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients." CMS

believes that for there to be "a change to the drug", there must be a drug that was marketed earlier than the drug that is a line extension of that drug.

CMS believe there may be some misunderstanding stemming from a comment and response in the December 31, 2020 Final Rule (2020 Final Rule). We received the following comments (see 85 Fed. Reg. 87043 (Dec. 31, 2020)):

> "A few commenters stated that CMS should make it clear that the original drug must be the ''truly original drug'' and identify that as the ''first drug approved.'' [We believe that] they wanted it specified that drugs that were approved after the initial drug but before the line extension are not to be treated as an initial brand name listed drug. [For example,] one commenter stated that the original drug should be based on the chronology of the approval of the original drug."

We responded:

> "In order to perform the calculation as instructed, all strengths of potential initial drugs must be considered, regardless of the chronology of a drug's approval, or date first marketed."

We intended the response to indicate that when manufacturers are evaluating potential initial drugs, they may need to consider several drugs marketed on different dates when determining what is the true initial drug. Regardless, the initial drug will have a market date that was earlier than the market date of the line extension drug.

Q9: If three drugs have the same market date and are identical except for the strength, are any of them a line extension?

A9: No, in order for there to be a change to the drug (i.e., a new formulation), there must be a drug with an earlier market date that could be considered the initial drug. If the three drugs are the first formulation of the drug, then none of the three drugs is a new formulation because they all have the same market date.

Q10: What if the three drugs in the prior scenario have different market dates, but the market dates are all within the same quarter? Are the two drugs with the later market dates a line extension of the drug with the earliest market date?

A10: No. If the market date of a drug being evaluated for identification as a line extension is within the same quarter or the immediately subsequent quarter as the market date of the potential initial drug, then the drug with the later market date will not be considered a line extension drug.

Q11: What if there are multiple changes to a drug over time so that several line extensions exist for a particular drug? How is it determined whether each version should be identified as a line extension?

A11: Each version of the drug should be evaluated to determine if it should be identified as a line extension. When doing the evaluation, the market dates should be included in the consideration for each drug. For example:

1. ABC 5mg tablet – market date 1/1/2000
2. ABC 10mg tablet – market date 1/1/2005
3. ABC 20mg tablet – market date 5/15/2005

ABC 10mg tablet is identified as a line extension of ABC 5mg tablet. ABC 20mg tablet is identified as a line extension of ABC 5mg tablet. ABC 20mg tablet does not consider ABC 10mg tablet as a potential initial drug. This is because the market date for ABC 20mg tablet is within the same or immediately subsequent quarter as the market date for ABC 10mg tablet.

Q12: The prior examples use the same drug with different strengths to demonstrate how to evaluate a drug for identification as a line extension. What if the drug being evaluated is the same strength, but in a different dosage form, or if there are other changes to the drug?

A12: The market date evaluation described above still applies. Although the examples given in the prior questions use different strengths of a drug to describe how to evaluate whether a drug is a line extension, the explanations apply to any change to a drug that qualifies the drug as a line extension.

Q13: In response to a comment in the preamble to the 2020 Final Rule (see page 87039), CMS stated that "[w]e believe that we have statutory authority to include new combination drugs and drug device combinations in the definition of new formulation; however, based on the comments, we have decided not to include a new combination of drugs, and a drug/device combination as a new formulation." Does that mean a manufacturer's combination drug, or drug/device combination should not be identified as a line extension?

A13: No, although CMS did not include a new combination of drugs and a drug/device combination in the definition of "new formulation," they are not excluded from the definition. The response to a comment from which the quote above was taken also specifically indicates, "It is important to note that combination drugs are not necessarily excluded from the definition of a new formulation." The full response reads:

> "We believe that we have statutory authority to include new combination drugs and drug device combinations in the definition of new formulation; however, based on the comments, we have decided not to include a new combination of drugs, and a drug/device combination as a new formulation. *It is important to note that combination drugs are not necessarily excluded from the definition of a new formulation. If an initial brand name listed drug is a combination of two or more drugs, and then a manufacturer begins selling a new formulation of that combination drug, then the new drug satisfies the definition of a new formulation and must be identified as a line extension* [emphasis added]. For example, consider two single-ingredient drugs, Alpha and Beta. A new combination of these two drugs, AlphaBeta, is not considered a new formulation for the

purposes of the line extension alternative rebate calculation. However, a later developed new formulation of AlphaBeta, for example, AlphaBeta XR, is a new formulation with AlphaBeta representing the initial brand name listed drug. Based on the comments received, we will not be finalizing our proposal that a drug that is a new combination is included in the definition of new formulation."

There are circumstances when a combination drug or a drug/device combination satisfies the definition and, therefore, must be reported as a line extension. See 85 Fed. Reg. 87039 for further discussion.

Q14: What if a manufacturer determines its drug is a line extension one quarter but not the next?

A14: Generally, if a drug satisfies the definition of line extension, it will always be a line extension. That does not mean, however, that there will always be an alternative URA calculation required. The alternative URA calculation can only be performed for a line extension drug if there is an initial drug to report for the applicable quarter.

Q15: What should a manufacturer do if it did not correctly identify an NDC as a line extension?

A15: A change request template for the product data needs to be submitted to the Division of Pharmacy. The template and instructions for its submission are found at Medicaid Drug Rebate Program Change Request | Medicaid.

Q16: On the product change request template, in the columns related to "LEDI" changes, it asks for the quarter, year, and initial drug NDC if applicable. When is it applicable to complete those fields?

A16: If a manufacturer is requesting a change to the "LEDI" field to be effective during the quarter that the request is submitted, generally, it is not necessary to complete those three fields on the template. Because the quarterly price reporting takes place during the 30 days after the close of the quarter, the manufacturer will report those fields as part of its quarterly price reporting for the current quarter.

If the requested effective quarter of the "LEDI" field change is in an earlier quarter, then for each quarter, beginning with the quarter in which the requested "LEDI" field change would be effective, through the quarter immediately preceding the current quarter, the manufacturer needs to complete a separate line on the template to identify the NDC of the initial drug (if any). For example, assume that the current quarter is 3Q2022. The manufacturer is requesting a change to the "LEDI" field from No to Yes with an effective quarter of 1Q2022. Because the manufacturer has presumably previously reported quarterly pricing for 1Q2022 and 2Q2022, without the initial drug information, it needs to provide the initial drug information for 1Q2022 and 2Q2022 on the template. The manufacturer will be able to report the initial drug information for 3Q2022 at the time it reports the quarterly pricing for 3Q2022.

III. Questions about the Initial Drug

Q17: What is the "ID Available for LE" field for?

A17: If, for the applicable quarter, there is an initial drug to report, this pricing field should be reported as "Yes" for that quarter. If there is no initial drug to report for the quarter, report "No" in this field.

Q18: What is the "Initial Drug" field for?

A18: The "Initial Drug" field identifies the NDC associated with the NDC defined as a line extension. As noted above, if a line extension drug has an initial drug to report for the applicable quarter, the "ID Available for LE" drug field should be populated with "Yes" and the NDC of the appropriate initial drug should be reported in the "Initial Drug" field. If the "ID Available for LE" drug field has been populated with "No", then the "Initial Drug" field should be left blank. The initial drug must be produced or distributed by a manufacturer with an active NDRA. Additionally, the initial drug should be manufactured by the same manufacturer as the line extension drug or by a manufacturer with a corporate relationship with the manufacturer of the line extension drug. 42 C.F.R. § 447.509(a)(4)(iv). If there is no initial drug for a line extension drug that satisfies these requirements in a quarter, then the "ID Available for LE" drug field should be populated with "No."

In order for a drug to qualify as an initial drug, the NDC must be active during the applicable quarter. That is, an initial drug being reported as part of the quarterly pricing data for a line extension drug must not be terminated in a quarter earlier than the quarter for which the pricing data for the line extension drug is being reported and certified.

For example, the labeler for a line extension drug, Drug B, is reporting 1Q2023 pricing information in April 2023. Drug B determines that Drug A is the initial drug. If Drug A has a termination date on or before 12/31/2022, the MDP system will not accept Drug A in the "Initial Drug" field for Drug B for 1Q2023 because Drug A was not active during 1Q2023. However, if the termination date of Drug A occurs at any time during 1Q2023 (e.g., termination date of 1/10/2023), the MDP system will allow Drug B to report Drug A as the "Initial Drug" field for 1Q2023.

Q19: Can an NDC that is identified as a line extension be reported as the initial drug for the same NDC?

A19: No, a drug cannot be a line extension of itself. (However, as described in a later example, a drug can be both a line extension and be reported as the initial drug for a different NDC.)

Q20: What if the standard rebate calculation for a line extension drug results in the highest URA as compared to the URAs generated by the alternative rebate calculation for each of the potential initial drugs?

A20: Even if the standard URA calculation results in the highest URA, a manufacturer should still identify the initial drug that has the highest additional rebate (calculated as a percentage of AMP) in the "Initial Drug" field for the quarter.

Q21: Why must a manufacturer report whether there is an initial drug on a quarterly basis? Why can't the manufacturer identify the initial drug for a line extension one time and then use that NDC as the initial drug for the corresponding line extension drug?

A21: The "ID available for LE" and "Initial Drug" fields are quarterly pricing fields and need to be evaluated every quarter. As there are many factors that go into the URA calculation, and they frequently change from quarter to quarter, it cannot be assumed that the initial drug will remain the same every quarter.

Q22: If a line extension drug is available in different strengths, and the alternative rebate calculation establishes the URA for a quarter, should the initial drug be the same for each strength of the line extension drug?

A22: If there are several strengths of a line extension drug and there are several potential initial drugs, we expect that the initial drug NDC will be the same for each strength of the line extension drug in a quarter. That is because the manufacturer must consider all drugs that could potentially be an initial drug for the line extension and choose the one with the highest additional rebate (calculated as a percentage of AMP).

Example:	Drug ABC 5mg	market date 1/1/2000
	Drug ABC 10mg	market date 1/1/2000
	Drug ABC XR 10mg	market date 1/1/2010 (Line Extension)
	Drug ABC XR 20mg	market date 1/1/2010 (Line Extension)

To identify which drug the manufacturer should report as the initial drug, it needs to look at all potential initial drugs. In this case, to determine the initial drug for both ABC XR 10mg and ABC XR 20mg, the manufacturer needs to look at both ABC 5mg and ABC 10mg. After the URA calculation is completed for these two potential initial drugs, the manufacturer should calculate which potential initial drug had a higher additional rebate (calculated as a percentage of AMP).[5] If, for example, it is determined that ABC 5mg has the higher additional rebate (calculated as a percentage of AMP), then ABC 5mg should be reported in the "Initial Drug" field for both strengths of the XR formulations.

Q23: If a drug has undergone several changes, so that there are numerous different formulations in the "family" of drugs, how does a manufacturer identify which drug is the initial drug to report?

[5] For a comprehensive explanation about how to perform this calculation, see: Federal Register :: Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs (84 Fed. Reg. 12130 (April 1, 2019)).

A23: For each drug that is a line extension, the manufacturer must consider all potential initial drugs. The NDC to report in the "Initial Drug" field is the NDC of the drug with the highest additional rebate (calculated as a percentage of AMP).

Example:	Drug ABC 5mg tablet	market date 1/1/2000
	Drug ABC 10mg tablet	market date 1/1/2005
	Drug ABC XR 10mg capsule	market date 1/1/2010
	Drug ABC XR 20mg capsule	market date 1/1/2010
	Drug ABC 10mg/5ml suspension	market date 1/1/2015

Other information to consider:

- Drug ABC 5mg tablet is not a line extension.
- Drug ABC 10mg tablet is a line extension that must consider Drug ABC 5mg tablet as a potential initial drug.
- Drug ABC XR 10mg capsule and Drug ABC XR 20mg capsule are line extensions that must consider Drug ABC 5mg tablet and Drug ABC 10mg tablet as potential initial drugs.
- Drug ABC 10mg/5ml suspension is a line extension drug that must consider all four of the previous NDCs as potential initial drugs.

To determine the initial drug to report for each line extension drug, the manufacturer should first calculate the standard URA for each of the NDCs that are potential initial drugs. The manufacturer should report in the "Initial Drug" field the NDC with the highest additional rebate (calculated as a percentage of AMP) out of all potential initial drugs for the line extension.

- For Drug ABC 10mg tablet, the only potential initial drug is ABC 5mg tablet. Therefore, ABC 5mg tablet is reported as the Initial drug for ABC 10mg tablet.
- For Drugs ABC XR 10mg capsule and ABC XR 20mg capsule, the manufacturer should determine whether ABC 5mg tablet or ABC 10mg tablet has the higher additional rebate (calculated as a percentage of AMP). If, for example, ABC 5mg tablet has a higher additional rebate (calculated as a percentage of AMP), then ABC 5mg tablet is reported in the "Initial Drug" field for ABC XR 10mg capsule and ABC XR 20mg capsule.
- For Drug ABC 10mg/5ml suspension, the manufacturer should determine which of the earlier four versions has the highest additional rebate (calculated as a percentage of AMP). If, for example, it is ABC XR 20mg capsule, then ABC XR 20mg capsule should be reported in the "Initial Drug" field to report for ABC 10mg/5ml suspension.

Q24: Can the same NDC be both an initial drug and a line extension?

A24: Yes, as demonstrated in the example above, Drug ABC 10mg is a line extension drug, and it can also be the initial drug for the line extension drugs that have a later market date.

Q25: If an NDC is reported as an initial drug but pricing has not been reported for the initial drug for the quarter, what happens?

A25: If a drug is identified as a line extension drug and the field "ID available for LE drug" is reported as "Yes" for a quarter, but the MDP system does not have the required information to be able to calculate an alternative URA:

For states: The "Product and URA" file provided to the states will contain a URA value of "zero" and an indicator of "1".

For manufacturers: The MDP system will display a "zero" URA and the "URA indicator" found on the "Maintain Quarterly Pricing" screen in the MDP system will have a value of "9", indicating that the line extension drug was missing the initial drug pricing. In such cases, the manufacturer must provide the correct pricing data so that a URA can be generated in the MDP system.

IV. Date issues

Q26: The 2020 Final Rule says that the regulatory definitions of line extension and new formulation take effect on January 1, 2022. What does that mean?

A26: Prior to January 1, 2022, manufacturers were advised to rely on the statutory definition of line extension at Section 1927(c)(2)(C) of the Act and use reasonable assumptions in their determination of whether their drug qualified as a line extension drug (81 Fed. Reg. 5265). Beginning on January 1, 2022, manufacturers should determine if their drug is a line extension drug consistent with the statute and the new regulatory definitions of line extension and new formulation. Regardless of whether a drug was identified as a line extension drug prior to January 1, 2022, if a drug is a line extension based on the regulatory definitions effective as of January 1, 2022, manufacturers should ensure drug product and pricing information is reported accurately and consistent with applicable laws and regulations.

Q27: If a drug was on the market prior to January 1, 2022, and the manufacturer determined it did not satisfy the definition of line extension prior to the effective date of the regulatory definition, does it need to be identified as a line extension if it satisfies the regulatory definition that took effect on January 1, 2022?

A27: If a drug satisfies the regulatory definition of line extension that took effect on January 1, 2022, it should be identified as a line extension beginning January 1, 2022. Regardless of prior status, CMS advises manufacturers that all drugs that are active in the MDP system be evaluated to determine whether they satisfy the applicable regulatory definitions and whether they must be reported as line extensions.

Q28: Assume a manufacturer determines its drug meets the definition of a line extension effective January 1, 2022, and requests CMS update the MDP system accordingly. If the manufacturer has a future need to restate the AMP and/or BP for quarters earlier than 1Q2022, will CMS treat that product as a line extension for the earlier quarters, or will this drug be treated as a line extension prospectively only, starting in 1Q2022?

A28: If a manufacturer determines a drug meets the definition of a line extension *only* effective 1Q2022, it will be treated as a line extension prospectively only. If the drug is a line extension drug in an earlier quarter, it should be identified as such, and the quarterly pricing for the earlier quarters should be reported with the data required for line extension drugs. If the drug is not identified as a line extension drug until 1Q2022, then the pricing data for line extension drugs is not required until pricing is due for that quarter, and the alternative URA calculation is not performed during quarters when the drug is not identified as a line extension, but only for quarters it is identified as a line extension.

V. Terminated Line Extension Drugs

Q29: How is the pricing record handled for the four quarters after termination of a line extension drug?

A29: When a drug is terminated, the last pricing record for the terminated drug is carried forward by the MDP system and copied to the four quarters after termination. Because the "ID Available for LE" field and the "Initial Drug" field are pricing data, the values reported and certified for the last active quarter of the line extension drug will be carried over for four quarters, along with the reported and certified AMP and BP. A URA will be calculated using that data along with the appropriate CPI-U value for the applicable quarter.