**Exception Scenarios for Products That Already Exist in DDR When the BBA ’15 Base AMP Field is Implemented:**

|  |  |
| --- | --- |
| **Scenario Description** | **How the BBA ’15 Base AMP Will be Established** |
| **#1** An NDC with a Market Date on or before April 1, 2013, has one package size and that package size was terminated in 3Q2014 (meaning that, in 3Q2014, more than four quarters had passed since the drug’s Termination Date quarter); therefore, the NDC does not have a 3Q2014 AMP. | If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC is active (due to the presence of a Reactivation Date that falls in a quarter after 3Q2014), CMS will expect the manufacturer to use reasonable assumptions to calculate a 3Q2014 pricing record for the NDC and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.**If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC has not yet been reactivated, a BBA ’15 Base AMP will not be established unless or until the NDC is eventually reactivated. If/when the NDC is reactivated, CMS will expect the manufacturer to use reasonable assumptions to calculate a 3Q2014 pricing record for the NDC. At the time that the NDC is reactivated in DDR, the manufacturer will be prompted to enter the 3Q2014 pricing record onto the *Manage Products* screen. DDR will then auto-populate the “BBA ’15 Base AMP” field with the reported 3Q2014 AMP. |
| **#2** An NDC with a Market Date on or before April 1, 2013, has multiple package sizes and every package size was either terminated during 3Q2014 (meaning that, in 3Q2014, more than four quarters had passed since each package size’s Termination Date quarter) or was not yet active in 3Q2014; therefore, the NDC does not have a 3Q2014 AMP. | If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, at least one package size is active (either due to the presence of a Reactivation Date that falls in a quarter after 3Q2014 or because a new package size has been reported with a Package Size Introduction Date that falls in a quarter after 3Q2014), CMS will expect the manufacturer to use reasonable assumptions to calculate a 3Q2014 pricing record for the NDC and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.**If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, every package size is inactive, a BBA ’15 Base AMP will not be established unless or until at least one package size is reactivated or a new package size is reported with a Package Size Introduction Date that falls in a quarter after 3Q2014. If/when the NDC is reactivated or a new package size is reported, CMS will expect the manufacturer to use reasonable assumptions to calculate a 3Q2014 pricing record for the NDC. At the time that the NDC is reactivated in DDR or a new package size is reported, the manufacturer will be prompted to enter the 3Q2014 pricing record onto the *Manage Products* screen. DDR will then auto-populate the “BBA ’15 Base AMP” field with the reported 3Q2014 AMP. |
| **#3** An NDC has a Market Date on or before April 1, 2013, and 3Q2014 is one of the four quarters after the NDC’s Termination Date quarter; therefore, the 3Q2014 AMP is an auto-populated value carried forward from the NDC’s last active quarter. | If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC is active (due to the presence of a Reactivation Date that falls after 3Q2014), CMS will expect the manufacturer to use reasonable assumptions to calculate a 3Q2014 pricing record for the NDC and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.**If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC has not yet been reactivated, a BBA ’15 Base AMP will not be established unless or until the NDC is eventually reactivated. If/when the NDC is reactivated, CMS will expect the manufacturer to use reasonable assumptions to calculate a 3Q2014 pricing record for the NDC. At the time that the NDC is reactivated in DDR, the manufacturer will be prompted to enter the 3Q2014 pricing record onto the *Manage Products* screen. DDR will then auto-populate the “BBA ’15 Base AMP” field with the reported 3Q2014 AMP. |
| **#4** An NDC has a Market Date on or before April 1, 2013, and a Purchased Product Date (PPD) equal to 4Q2014 or later (as a result of one company purchasing or otherwise acquiring an NDC from another company, or transferring an NDC from one of its labeler codes to another); therefore, the NDC does not have a 3Q2014 AMP. | Consistent with the way that the OBRA ’93 Base AMP is currently established for S/I drugs that have a PPD, CMS will expect the manufacturer to report a 3Q2014 pricing record so that a BBA ’15 Base AMP can be established. Consequently, if a manufacturer has purchased or otherwise acquired an N drug from another company in a quarter after 3Q2014, we remind such manufacturers to reach out to the selling company for this pricing information as soon as possible to ensure they can report it when the “BBA ’15 Base AMP” field is implemented. **Upon the field’s implementation, all active N drugs with a Market Date on or before April 1, 2013, and a PPD equal to 4Q2014 or later will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#5** An NDC has a Market Date on or before April 1, 2013; however, the drug was terminated during 3Q2014 and eventually re-introduced under a different NDC. The new NDC was reported with a PPD equal to 4Q2014 or later; therefore, the NDC does not have a 3Q2014 AMP. | CMS will expect the manufacturer to use reasonable assumptions to calculate a 3Q2014 pricing record for the re-designated NDC and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs with a Market Date on or before April 1, 2013, and a PPD equal to 4Q2014 or later will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#6** An NDC has a Market Date on or before April 1, 2013, and both the NDC and the labeler code are currently active; however, the NDC is missing a 3Q2014 pricing record because one was never reported. | Manufacturers with N drugs that fall under this scenario have already been contacted by CMS with a request to report the missing 3Q2014 pricing record as soon as possible. **If the missing pricing has not been reported by the time that the “BBA ’15 Base AMP” field is implemented, the drug will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. In addition, a value of “Not Yet Reported” will appear in the “BBA ’15 Base AMP” field until the missing pricing has been reported. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#7** An NDC has a Market Date on or before April 1, 2013, and the labeler code’s Optional Effective Date (OED) falls within 4Q2014 or later; therefore, the NDC does not have a 3Q2014 AMP. | Consistent with the way that the OBRA ’93 Base AMP is currently established for S/I drugs of manufacturers that have an OED after the OBRA ’93 Base AMP quarter, manufacturers will be expected to report a 3Q2014 pricing record when the “BBA ’15 Base AMP” field is implemented. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#8** An NDC has a Market Date on or before April 1, 2013, but the NDC was deleted from the MDRP prior to the implementationof the “BBA ’15 Base AMP” field. | The NDC will not have a BBA ’15 Base AMP unless CMS restores the NDC, at which time the “BBA ’15 Base AMP” field will be auto-populated in accordance with the specifications described in this document. **Upon the field’s implementation, all active N drugs that fall under this scenario will be made out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#9** An NDC has a Market Date on or before April 1, 2013, but the labeler code was terminated prior to the implementation of the “BBA ’15 Base AMP” field, and a 3Q2014 pricing record was never reported.  | The NDC will not have a BBA ’15 Base AMP unless the manufacturer requests reinstatement into the MDRP. If/when the manufacturer requests to be reinstated, CMS will require the manufacturer provide the missing 3Q2014 pricing record as part of the reinstatement process. |
| **#10** An NDC has a Market Date on or before April 1, 2013, and a BBA ’15 Base AMP is established using the drug’s existing 3Q2014 pricing record; however, a subsequent change to the NDC’s Market Date, OED, PPD and/or Termination/Reactivation dates makes the drug inactive during 3Q2014.  | DDR will retain the 3Q2014 pricing record on which the BBA ’15 Base AMP was based. All other affected pricing will be deleted from DDR (and MDR) in accordance with current business rules.  |
| **#11** An NDC has a Market Date after April 1, 2013, but the pricing record for the fifth full quarter after the Market Date quarter is missing because it was never reported. Consequently, there is no quarterly AMP from which a BBA ’15 Base AMP can be established. | Manufacturers with N drugs that fall under this scenario have already been contacted by CMS with a request to report the missing pricing record as soon as possible. **If the missing pricing has not been reported by the time that the “BBA ’15 Base AMP” field is implemented, the drug will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or update to existing monthly/quarterly pricing will be permitted for the NDC until the missing pricing record is submitted and certified. Once the missing pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#12** An NDC has a Market Date after April 1, 2013, but the fifth full quarter after the Market Date quarter falls prior to the NDC’s PPD (and the PPD results from one company purchasing or otherwise acquiring an NDC from another company, or transferring an NDC from one of its labeler codes to another); therefore, no pricing record exists for the fifth full quarter after the Market Date quarter. | Consistent with the way that OBRA ’93 Base AMP is currently established for S/I drugs that have a PPD, manufacturers will be expected to report the pricing record for the fifth full quarter after the Market Date quarter, including a quarterly AMP. Consequently, if a manufacturer has purchased or otherwise acquired an N drug with a Market Date after April 1, 2013, from another company, we remind such manufacturers to reach out to the selling company for this pricing information as soon as possible to ensure they can report it when the BBA ’15 Base AMP field is implemented. **Upon the field’s implementation, all active N drugs with a Market Date after April 1, 2013, and a PPD that falls in a quarter after the fifth full quarter after the Market Date quarter, will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updated to existing monthly/quarterly pricing will be permitted for the NDC until the missing pricing record is submitted and certified. Once the missing pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#13** An NDC has a Market Date after April 1, 2013; however, the drug was terminated during the fifth full quarter after the Market Date quarter and eventually re-introduced under a new NDC. The new NDC was reported with a PPD equal to the sixth full quarter after the Market Date quarter or later; therefore, no pricing record exists for the fifth full quarter after the Market Date quarter. | CMS will expect the manufacturer to use reasonable assumptions to calculate a quarterly pricing record for the fifth full quarter after the Market Date quarter for the re-introduced NDC and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs with a Market Date after April 1, 2013, and a PPD that falls in a quarter after the fifth full quarter after the Market Date quarter, will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing 3Q2014 pricing record is submitted and certified. Once the 3Q2014 pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#14** An NDC has a Market Date after April 1, 2013, but the fifth full quarter after the Market Date quarter falls before the labeler code’s OED quarter; therefore, no pricing record exists for the fifth full quarter after the Market Date quarter. | Consistent with the way that OBRA ’93 Base AMP is currently established for S/I drugs of manufacturers that have an OED after the OBRA ’93 Base AMP quarter, manufacturers will be expected to report a pricing record for the fifth full quarter after the Market Date quarter. **Upon the BBA ’15 Base AMP field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing pricing record is submitted and certified. Once the missing pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#15** An NDC with a Market Date after April 1, 2013, has one package size and that package size was terminated in the fifth full quarter after the Market Date quarter (meaning that, in the fifth full quarter after the NDC’s Market Date quarter, more than four quarters had passed since the drug’s Termination Date quarter); therefore, no pricing record exists for the fifth full quarter after the Market Date quarter. | If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC is active (due to the presence of a Reactivation Date that falls in a quarter after the fifth full quarter after the Market Date quarter), CMS will expect the manufacturer to use reasonable assumptions to calculate a pricing record for the fifth full quarter after the Market Date quarter and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing pricing record is submitted and certified. Once the pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.**If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC has not yet been reactivated, a BBA ’15 Base AMP will not be established unless or until the NDC is eventually reactivated. If/when the NDC is reactivated, CMS will expect the manufacturer to use reasonable assumptions to calculate a pricing record for the fifth full quarter after the Market Date quarter. At the time that the NDC is reactivated in DDR, the manufacturer will be prompted to enter the pricing record for the fifth full quarter after the Market Date quarter onto the *Manage Products* screen. DDR will then auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP. |
| **#16** An NDC with a Market Date after April 1, 2013, has multiple package sizes and every package size was either terminated during the fifth full quarter after the Market Date quarter (meaning that, in the fifth full quarter after the Market Date quarter, more than four quarters had passed since the drug’s Termination Date quarter) or was not yet active in the fifth full quarter after the Market Date quarter; therefore, no pricing record exists for the fifth full quarter after the Market Date quarter. | If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, at least one package size is active (either due to the presence of a Reactivation Date that falls in a quarter after the fifth full quarter after the Market Date quarter or because a new package size has been reported with a Package Size Introduction Date that falls in a quarter after the fifth full quarter after the Market Date quarter), CMS will expect the manufacturer to use reasonable assumptions to calculate a pricing record for the fifth full quarter after the Market Date quarter and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing pricing record is submitted and certified. Once the pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.**If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, every package size is inactive, a BBA ’15 Base AMP will not be established unless or until at least one package size is reactivated or a new package size is reported with a Package Size Introduction Date that falls in a quarter after the fifth full quarter after the Market Date quarter. If/when the NDC is reactivated or a new package size is reported, CMS will expect the manufacturer to use reasonable assumptions to calculate a pricing record for the fifth full quarter after the Market Date quarter. At the time that the NDC is reactivated in DDR or a new package size is reported, the manufacturer will be prompted to enter the pricing record onto the *Manage Products* screen. DDR will then auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP. |
| **#17** An NDC with a Market Date after April 1, 2013, has a Termination Date such that the fifth full quarter after the Market Date quarter is one of the four quarters after the NDC’s Termination Date quarter; therefore, the AMP for the fifth full quarter after the Market Date quarter is an auto-populated value carried forward from the NDC’s last active quarter. | If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC is active (due to the presence of a Reactivation Date that falls in a quarter after the fifth full quarter after the Market Date quarter), CMS will expect the manufacturer to use reasonable assumptions to calculate a pricing record for the fifth full quarter after the Market Date quarter and then report that pricing in DDR. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing pricing record is submitted and certified. Once the pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.**If, at the time that the “BBA ’15 Base AMP” field is implemented in DDR, the NDC has not yet been reactivated, a BBA ’15 Base AMP will not be established unless or until the NDC is eventually reactivated. If/when the NDC is reactivated, CMS will expect the manufacturer to use reasonable assumptions to calculate a pricing record for the fifth full quarter after the Market Date quarter. At the time that the NDC is reactivated in DDR, the manufacturer will be prompted to enter the pricing record for the fifth full quarter after the Market Date quarter onto the *Manage Products* screen. DDR will then auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP. |
| **#18** An NDC has a Market Date after April 1, 2013; however, the fifth full quarter after the Market Date quarter has not yet occurred (e.g., if an NDC has a Market Date of 10/2/2016, the fifth full quarter will be 1Q2018, which is in the future). | The NDC will not have a BBA ’15 Base AMP until the manufacturer reports the quarterly pricing record for the fifth full quarter after the Market Date quarter. Once the pricing record for the fifth full quarter after the Market Date quarter has been reported and certified, DDR will auto-populate that value in the “BBA ’15 Base AMP” field. **NOTE:** Until a quarterly pricing record for the fifth full quarter after an NDC’s Market Date quarter has been reported and certified, no additional rebate will be calculated from the Market Date quarter through the fourth after the Market Date quarter. Once the quarterly record has been reported and certified, the established BBA ’15 Base AMP will be used to perform the additional rebate portion of the URA calculation beginning with the fifth full quarter after the Market Date quarter. The established BBA ’15 Base AMP will not be retroactively used in the URA calculation from the Market Date quarter through the fourth after the Market Date quarter. |
| **#19** An NDC has a Market Date after April 1, 2013; however, the NDC was deleted from the MDRP prior to the implementation of the “BBA ’15 Base AMP” field. | The NDC will not have a BBA ’15 Base AMP unless CMS restores the NDC. If the NDC is eventually restored, the “BBA ’15 Base AMP” field will be auto-populated in accordance with the specifications described in this document. **Upon the field’s implementation, all active N drugs that fall under this scenario will be shown as out of compliance in DDR, and no initial monthly/quarterly pricing or updates to existing monthly/quarterly pricing will be permitted for the NDC until the missing pricing record is submitted and certified. Once the pricing record has been submitted, DDR will auto-populate the “BBA ’15 Base AMP” field with the reported quarterly AMP value.** |
| **#20** An NDC has a Market Date after April 1, 2013, and should have a quarterly pricing record for the fifth full quarter after the Market Date quarter; however, the manufacturer is terminated from the MDRP and that quarterly pricing record was never reported. | The NDC will not have a BBA ’15 Base AMP; however, if the manufacturer requests reinstatement into the MDRP, CMS will require the manufacturer to report the missing pricing record as part of the reinstatement process. |
| **#21** An NDC has a Market Date after April 1, 2013, and a BBA ’15 Base AMP is established using the drug’s existing pricing record for the fifth full quarter after the Market Date quarter. However, a subsequent change to the NDC’s OED, PPD and/or Termination/Reactivation dates makes the drug invalid during the fifth full quarter after the Market Date quarter. | DDR will retain the pricing record on which the BBA ’15 Base AMP was based (i.e., the pricing record for the fifth full quarter after the Market Date quarter). All other affected pricing will be deleted from DDR (and MDR) in accordance with current business rules.  |