

Acute Hospitals – Billing Instructions for Carve-Out Drugs

Updated September 18, 2018

INTRODUCTION

Pursuant to **Sections 5.B.8.b** and **5.C.9** of the current MassHealth Acute Hospital Request for Applications (as amended from time to time, the “**Acute Hospital RFA**” or “**RFA**”) applicable to in-state providers, and as applicable to out-of-state acute hospital providers pursuant to regulations at **130 CMR 450.233(D)**, participating in-state and out-of-state MassHealth Acute Hospital providers will be paid for “**APAD Carve-Out Drugs**” (**inpatient**) and “**APEC Carve-Out Drugs**” (**outpatient**) in accordance with the in-state acute hospital methodology for such drugs, which is set forth in the Acute Hospital RFA.¹ To ensure proper payment, Hospitals **must** follow **special billing instructions, which are set forth below**. Failure to follow these special billing instructions could result in an overpayment that will be subject to recoupment, and could subject the provider to sanctions for improper billing.

**These billing instructions may be updated from time to time.*

I. IDENTIFICATION OF CARVE-OUT DRUGS

The EOHHS-designated **APAD Carve-Out Drugs** and **APEC Carve-Out Drugs** that are subject to these billing instructions are identified on the “**MassHealth Acute Hospital Carve-Out Drugs List**” within the MassHealth Drug List (**MHDL**), which is published at <https://masshealthdruglist.ehs.state.ma.us/MHDL/welcome.do>.²

FDA-approved new-to-market drugs and biologics that are not listed in the MHDL will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the drug or biologic. Hospitals should contact MassHealth regarding whether a new-to-market drug not listed in the MHDL is an “APAD Carve-Out Drug” or an “APEC Carve-Out Drug” for purposes of the Acute Hospital RFA (or MassHealth regulations, as applicable) and these instructions.

II. OTHER REQUIREMENTS AND CONDITIONS OF PAYMENT

Other requirements and conditions of payment apply to Hospitals for APAD Carve-Out Drugs and APEC Carve-Out Drugs that are not included here. For example, special requirements apply regarding (1) prior authorization, (2) preadmission screening (as applicable), and (3) reporting of efficacy and member progress as a result of being treated with the drug in question. *Some of these requirements for APAD Carve-Out Drugs and APEC Carve-Out Drugs may differ substantially from the requirements for other drugs.*

Acute Hospitals should, therefore, review these billing instructions **in concert with** the Acute Hospital RFA (including Sections 5.B.8.b and 5.C.9), the MassHealth Acute Hospital Carve-Out Drugs List of the MHDL and related prior authorization approval criteria, applicable MassHealth regulations, and other relevant MassHealth policy statements and requirements.

¹ The payment method for APAD Carve-Out Drugs is in Section 5.B.8.b of the RFA, and the payment method for APEC Carve-Out Drugs is in Section 5.C.9 of the RFA.

² **NOTE:** EOHHS may update this list at any time. Hospitals may sign up to receive e-mail notifications when updates to the MHDL are posted on the web, by enrolling at this website location.

IMPORTANT: To ensure compliance with these billing instructions, the Hospital’s billing department or agents that submit claims to MassHealth must coordinate, as appropriate, with Hospital personnel or agents that handle the Hospital’s payment arrangements with the drug manufacturer (or other party) for these APAD Carve-Out Drugs and APEC Carve-Out Drugs, and with the clinical staff that handles the Hospital’s prior authorization requests to the MassHealth Drug Utilization Review (DUR) Program, for these drugs.

III. BILLING INSTRUCTIONS FOR APAD CARVE-OUT DRUGS (acute inpatient hospitals)

The following **billing instructions** apply to inpatient claims for APAD Carve-Out Drugs submitted by **Acute Inpatient Hospitals (Provider Type 70)**, referred to as “Hospitals” in this **Part III**.

1. Special Requirements for Transmitting Claims for APAD Carve-Out Drugs:

- a. Costs, charges, and any other claims-based data corresponding to the APAD Carve-Out Drug **must be excluded from any facility/institutional claim** (including Claim Types I and A) that the Hospital submits for the member’s stay.
- b. The Hospital must instead claim separate payment for APAD Carve-Out Drugs **on a professional claim (Claim Types M and B)**, via Direct Data Entry (DDE)³ **and include Delay Reason Code 11.**
- c. Along with the member’s name, date(s) of service, and other usual information, the separate DDE claim for the APAD Carve-Out Drug **must also** include:
 - (i) the appropriate **National Drug Code (NDC)** identifier and corresponding **HCPCS code(s)** for the drug; **and**
 - (ii) the **number of units** of the drug administered to the member that is covered by the claim.
- d. The Hospital **must** also include the following as separate attachments to the claim for the APAD Carve-Out Drug, which MassHealth shall deem incorporated into and part of the claim:
 - (i) a **statement of the Hospital's actual acquisition cost** of the drug (as defined in #2, below) used to treat the member, appropriately verified; and
 - (ii) a **copy of the invoice(s)** for the APAD Carve-Out Drug from the drug manufacturer, supplier, distributor, or other similar party or agent; and
 - (iii) if applicable, **any other documentation that is necessary** for the Hospital **to evidence** that the amount listed on the attachment(s) to the DDE claim (referenced in #1.d.(i), above) is the Hospital's **actual acquisition cost** of the APAD Carve-Out Drug (as defined in #2, below). **NOTE:** MassHealth may require additional documentation upon receipt of the claim, if necessary to evidence this.
- e. **See also important instructions in #3, below**, regarding the timing of submitting the claim if the Hospital is party to, or a direct beneficiary of, a “**Performance-Based Guarantee**” (as referenced in #3).

2. Definition of “actual acquisition cost” for purposes of these instructions:

For purposes of these instructions, the Hospital’s “**actual acquisition cost**” of the APAD Carve-Out Drug is defined as follows:

³ In the unlikely event that a provider meets the MassHealth requirements of a paper submission waiver request, the provider should contact the MassHealth Customer Service Center for instructions about how to submit a claim for an APAD Carve-Out Drug on the 1500 paper claim.

“the Hospital’s invoice price for the drug, **net of all** on-or-off invoice reductions, discounts, rebates, charge backs and similar adjustments that the Hospital has or will receive from the drug manufacturer or other party for the drug that was administered to the Member while the member was admitted in the Hospital, including any efficacy-, outcome-, or performance-based guarantees (or similar arrangements), whether received pre- or post-payment.”

3. Timing of Claims Submission for APAD Carve-Out Drug under Special Circumstances:

For purposes of these instructions, a **“Performance-Based Guarantee”** refers to any **efficacy-, outcome-, or performance-based guarantee (or similar arrangement)** from the drug manufacturer (or other party) to the Hospital that applies to the treatment of the member with the APAD Carve-Out Drug in question, whether or not such an arrangement is required by EOHHS.

- a. Subject to the requirements in 130 CMR 450.309, in the event the **Hospital is a party to or a direct beneficiary of a Performance-Based Guarantee from the drug manufacturer (or other party)**, and the terms of the Performance-Based Guarantee allow the Hospital to pay in full or in part for the APAD Carve-Out Drug **only if** certain conditions are met (e.g., the Hospital is only required to pay for the drug if the member goes into remission), the Hospital **must not** submit a claim to MassHealth for the APAD Carve-Out Drug **until** the Hospital actually makes the payment it will be required to make to the drug manufacturer or other party (and must **not** submit **any** claim for the drug to MassHealth in the event it is not ultimately required to pay for the drug).
- b. If any other Performance-Based Guarantee (or similar arrangement, or other cost reduction) is triggered to the financial benefit of the Hospital **after** the Hospital submits a claim to MassHealth for the APAD Carve-Out Drug, follow the instructions in #4, below.
- c. If, by following the instructions in #3.a, above, the Hospital’s DDE claim for the APAD Carve-Out Drug (if any) will be submitted **more than 90 days after the date of service** (as described in 130 CMR 450.309), the Hospital **must** submit a request to MassHealth for a 90-day waiver via DDE on the Provider Online Service Center (POSC) along with the claim submission using the **MassHealth 90-Day Waiver Request Form** (check “Other” as the Reason for the Request, and otherwise follow the instructions). Refer to All Provider Bulletin 233, February 2013 for specific instructions. The current form may be retrieved at https://www.mass.gov/files/2017-07/90-dwr_0.pdf.

4. Requirement to Notify MassHealth and Adjust or Modify Claim for APAD Carve-Out Drug:

In the event that any **Performance-Based Guarantee, or any other financial benefit or cost reduction**, from the drug manufacturer (or other party) **is triggered** to the financial benefit of the Hospital for the APAD Carve-Out Drug **after the Hospital has submitted a claim** to MassHealth for the drug (**or** the Hospital otherwise becomes aware that it previously submitted a claim to MassHealth that incorrectly specified an amount that exceeded the Hospital’s actual acquisition cost of the APAD Carve-Out Drug (as defined in #2, above)):

- a. the Hospital must **immediately notify EOHHS** in writing **by e-mail** using the following address: Carve-OutDrugBilling@MassMail.State.MA.US and include "**Acute Hospital Carve-Out Drug Follow-Up**" in the subject line, specifying the drug in question; **and**
- b. the Hospital must **adjust or modify the submitted claim in the manner specified by EOHHS** to account for the financial benefit (or to correct the error, if applicable) to ensure that the full financial benefit has been passed back to MassHealth (or the error, if applicable, is otherwise corrected). In particular, if such claim has processed to a paid status, the Hospital must

immediately adjust (or void) the claim to correctly reduce (or eliminate) payment, as applicable, consistent with the financial benefit (or in order to correct the error, if applicable).

5. Other General Billing Instructions:

With the exception of the instructions set forth above, all other applicable MassHealth billing instructions and conditions of payment continue to apply. MassHealth may, on a case-by-case basis, provide additional or different instructions for submitting claims for APAD Carve-Out Drugs in certain circumstances (e.g., if MassHealth deems it necessary or desirable to address new innovative payment structures from the drug manufacturer (or other party) that may be available for the APAD Carve-Out Drug, or to implement CMS guidance that may apply to the APAD Carve-Out Drug).

6. Claims Adjudication:

Claims for APAD Carve-Out Drugs submitted using the instructions set forth above will suspend for review and pricing by MassHealth in accordance with the payment methodology described in **Section 5.B.8.b** of the Acute Hospital RFA.⁴ Upon completion of the steps above, MassHealth will release the claim to complete its adjudication.

IV. BILLING INSTRUCTIONS FOR APEC CARVE-OUT DRUGS (acute outpatient hospitals)

The following **billing instructions** apply to **outpatient claims for APEC Carve-Out Drugs** submitted by **Acute Outpatient Hospitals and Hospital Licensed Health Centers (Provider Types 80 and 81)**, referred to as “Hospitals” in this **Part IV**.

1. Special Requirements for Transmitting Claims for APEC Carve-Out Drugs:

- a. The Hospital must **claim separate payment** for APEC Carve-Out Drugs on a **facility/institutional claim (Claim Types O and C)**, **via Direct Data Entry (DDE)**⁵ **and** include **Delay Reason Code 11**.
- b. This DDE facility/institutional **claim for the APEC Carve-Out Drug must be separate** from any facility/institutional claim the Hospital submits for **all other** acute outpatient hospital services delivered to the member during the same visit. The Hospital **must exclude** all costs, charges, and any other claims-based data **corresponding to the APEC Carve-Out Drug from the** facility/institutional **claim** that the Hospital submits **for those other (non-APEC Carve-Out Drug)** services.
- c. Along with the member’s name, date(s) of service, and other usual information, the DDE **claim for the APEC Carve-Out Drug must** also include:
 - (i) the appropriate **National Drug Code (NDC)** identifier and corresponding **HCPCS code(s)** for the drug; **and**
 - (ii) the **number of units** of the drug administered to the member that is covered by the claim.
- d. The Hospital **must** also include **the following as separate attachments** to the claim for the APEC Carve-Out Drug, which MassHealth shall deem incorporated into and part of the claim:

⁴ **Section 5.B.8.b** of the RFA provides that Hospitals will be paid **the lowest of** (1) the Hospital’s “actual acquisition cost” of the drug, (2) the drug’s wholesale acquisition cost, and (3) the Medicare Part B rate for the drug (if available), each as determined by EOHHS.

⁵ In the unlikely event that a provider meets the MassHealth requirements of a paper submission waiver request, the provider should contact the MassHealth Customer Service Center for instructions about how to submit a claim for an APEC Carve-Out Drug on the UB04 paper claim.

- (i) a **statement of the Hospital's actual acquisition cost** of the drug (as defined in #2, below) used to treat the Member, appropriately verified; and
 - (ii) a **copy of the invoice(s)** for the APEC Carve-Out Drug from the drug manufacturer, supplier, distributor, or other similar party or agent; and
 - (iii) If applicable, **any other documentation that is necessary** for the Hospital to evidence that the amount listed on the attachment to the DDE claim (referenced in #1.d(i), above) is the Hospital's **actual acquisition cost** of the APEC Carve-Out Drug (as defined in #2, below). **NOTE:** MassHealth may require additional documentation upon receipt of the claim, if necessary to evidence this.
- e. **See also important instructions in #3, below**, regarding the timing of submitting the claim if the Hospital is a party to, or direct beneficiary of, a **"Performance-Based Guarantee"** (as referenced in #3).

2. Definition of "actual acquisition cost" for purposes of these instructions.

For purposes of these instructions, the Hospital's **"actual acquisition cost" of the APEC Carve-Out Drug** is defined as follows:

"the Hospital's invoice price for the drug, **net of all** on-or-off invoice reductions, discounts, rebates, charge backs and similar adjustments that the Hospital has or will receive from the drug manufacturer or other party for the drug that was administered to the Member during an Acute Outpatient Hospital visit, including any efficacy-, outcome-, or performance-based guarantees (or similar arrangements), whether received pre- or post-payment."

3. Timing of Claims Submission for APEC Carve-Out Drugs under Special Circumstances:

For purposes of these instructions, a **"Performance-Based Guarantee"** refers to any **efficacy-, outcome-, or performance-based guarantee (or similar arrangement)** from the drug manufacturer (or other party) to the Hospital that applies to the treatment of the member with the APEC Carve-Out Drug in question, whether or not such an arrangement is required by EOHHS.

- a. Subject to the requirements in 130 CMR 450.309, in the event the **Hospital is a party to or a direct beneficiary of a Performance-Based Guarantee from the drug manufacturer (or other party)**, and the terms of the Performance-Based Guarantee allow the Hospital to pay in full or in part for the APEC Carve-Out Drug **only if** certain conditions are met (e.g., the Hospital is only required to pay for the drug if the member goes into remission), the Hospital **must not** submit a claim to MassHealth for the APEC Carve-Out Drug **until** the Hospital actually makes the payment it will be required to make to the drug manufacturer or other party (and **must not** submit **any** claim for the drug to MassHealth in the event it is not ultimately required to pay for the drug).
- b. If any other Performance-Based Guarantee (or similar arrangement, or other cost reduction) is triggered to the financial benefit of the Hospital **after** the Hospital submits a claim to MassHealth for the APEC Carve-Out Drug, follow the instructions in #4, below.
- c. If, by following the instructions in #3.a, above, the Hospital's DDE claim for the APEC Carve-Out Drug (if any) will be submitted **more than 90 days after the date of service** (as described in 130 CMR 450.309), the Hospital **must** submit a request to MassHealth for a 90-day waiver via DDE on the Provider Online Service Center (POSC) along with the claim submission using the **MassHealth 90-Day Waiver Request Form** (check "Other" as the Reason for the Request, and otherwise follow

the instructions). Refer to All Provider Bulletin 233, February 2013 for specific instructions. The current form may be retrieved at https://www.mass.gov/files/2017-07/90-dwr_0.pdf

4. Requirement to Notify MassHealth and Adjust or Modify Claim for APEC Carve-Out Drug:

In the event that any **Performance-Based Guarantee, or any other financial benefit or cost reduction**, from the drug manufacturer (or other party) **is triggered** to the financial benefit of the Hospital for the APEC Carve-Out Drug **after the Hospital has submitted a claim** to MassHealth for the drug (or the Hospital otherwise becomes aware that it previously submitted a claim to MassHealth that incorrectly specified an amount that exceeded the Hospital's actual acquisition cost of the APEC Carve-Out Drug (as defined in #2, above)):

- a. the Hospital must **immediately notify EOHHS** in writing **by e-mail** using the following address: Carve-OutDrugBilling@MassMail.State.MA.US and include "**Acute Hospital Carve-Out Drug Follow-Up**" in the subject line, specifying the drug in question; **and**
- b. the Hospital must **adjust or modify the submitted claim in the manner specified by EOHHS** to account for the financial benefit (or to correct the error, if applicable) to ensure that the full financial benefit has been passed back to MassHealth (or the error, if applicable, is otherwise corrected). In particular, if such claim has processed to a paid status, the Hospital must immediately adjust (or void) the claim to correctly reduce (or eliminate) payment, as applicable, consistent with the financial benefit (or in order to correct the error, if applicable).

5. Other General Billing Instructions:

With the exception of the instructions set forth above, all other applicable MassHealth billing instructions and conditions of payment continue to apply. MassHealth may, on a case-by-case basis, provide additional or different instructions for submitting claims for APEC Carve-Out Drugs in certain circumstances (e.g., if MassHealth deems it necessary or desirable to address new innovative payment structures from the drug manufacturer (or other party) that may be available for the APEC Carve-Out Drug, or to implement CMS guidance that may apply to the APEC Carve-Out Drug).

6. Claims Adjudication:

Claims for APEC Carve-Out Drugs submitted using the instructions set forth above will suspend for review and pricing by MassHealth in accordance with the payment methodology described in **Section 5.C.9** of the Acute Hospital RFA.⁶ Upon completion of the steps above, MassHealth will release the claim to complete its adjudication.

⁶ **Section 5.C.9** of the RFA provides that Hospitals will be paid **the lowest of** (1) the Hospital's "actual acquisition cost" of the drug, (2) the drug's wholesale acquisition cost, and (3) the Medicare Part B rate for the drug (if available), each as determined by EOHHS.