MassHealth Acute Hospital Carve-Out Drugs List

This MassHealth Acute Hospital Carve-Out Drugs List section of the MassHealth Drug List (MHDL) applies to participating in-state MassHealth Acute Hospital providers, and as applicable to out-of-state MassHealth acute hospital providers pursuant to 130 CMR 450.233(D). This List identifies the current list of "**Adjudicated Payment Amount per Discharge (APAD) Carve-Out Drugs**" and "**Adjudicated Payment per Episode of Care (APEC) Carve-Out Drugs**" for purposes of Sections 5.B.8.b and 5.C.9 of the current MassHealth Acute Hospital Request for Applications for in-state acute hospitals (Acute Hospital RFA), and regulations at 130 CMR 450.233(D) for out-of-state acute hospitals.

The hospital must obtain prior authorization (PA) from MassHealth for the APAD Carve-Out Drugs and APEC Carve-Out Drugs on this list, and the associated treatment will be subject to monitoring, as indicated below. Other requirements also apply. This list, and the PA and other requirements, may be updated from time to time.

Hospitals should also review any special billing instructions for APAD Carve-Out Drugs and APEC Carve-Out Drugs posted on the "Billing Tips" section of the MassHealth website.

I. APAD Carve-Out Drugs (administered in an *acute inpatient hospital* setting)

The drugs and biologics listed in this Part I are "**APAD Carve-Out Drugs**" for purposes of Section 5.B.8.b of the Acute Hospital RFA and MassHealth regulations at 130 CMR 450.233(D). The APAD Carve-Out Drugs will be listed alphabetically by therapeutic class, then by the name of the drug or drug ingredients.

Prescriber must submit a request for PA using a Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved. Should PA be granted, the admitting provider must then submit a preadmission screening request for the acute inpatient hospital admission to the MassHealth acute hospital utilization review contractor, Permedion, in accordance with applicable MassHealth regulations and guidelines. Once both have been approved, the treatment plan can be initiated.

Please note that, in addition to PA and other requirements, these therapies require both short- and long-term monitoring for efficacy and durability of response. MassHealth will be conducting outreach to prescriber's offices to gather the applicable information.

CAR-T Therapies

See Therapeutic Class Table 75 on the MassHealth Drug List for additional information on CAR-T Therapies, including approval criteria and monitoring parameters

- Kymriah (tisagenlecleucel) – **PA****
  *** Please note that PA approval will require a letter from the hospital's financial department addressing participation status in the manufacturer's outcomes-based contract.*

- Tecartus (brexucabtagene autoleucel) – **PA**
- Yescarta (axicabtagene ciloleucel) – **PA**

Process: Prescriber must submit a request for PA for the CAR-T therapy to MassHealth using the Chimeric Antigen Receptor (CAR)-T Immunotherapies Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated. MassHealth will then conduct ongoing monitoring of the treatment, based on parameters including: dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; and response to therapy (e.g., complete blood count, bone marrow blasts, peripheral blood blasts, platelets, absolute neutrophil counts). See MassHealth Chimeric Antigen Receptor (CAR)-T Immunotherapies Monitoring Program document on the MassHealth Drug List for additional information.

Inherited Retinal Disease Gene Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Luxturna, including approval criteria and monitoring parameters

- Luxturna (voretigene neparvovec) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Luxturna Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated. MassHealth will then conduct ongoing monitoring of the treatment, based on parameters that may include: dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; and response to therapy (e.g., full-field light sensitivity threshold [FST] scores). See MassHealth Luxturna Monitoring Program document on the MassHealth Drug List for additional information.

Spinal Muscular Atrophy Gene Therapy

See Therapeutic Class Table 76 on the MassHealth Drug List for additional information on Zolgensma, including approval criteria and monitoring parameters

- Zolgensma (onasemnogene abeparvovec-xioi) – **PA**

Process: Prescriber must submit a request for PA using the Neuromuscular Agents Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated. MassHealth will then conduct ongoing monitoring of the treatment, based on parameters that may include: dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; and response to therapy (e.g., updates of clinically

appropriate motor function tests). See MassHealth Zolgensma Monitoring Program document on the MassHealth Drug List for additional information.

MassHealth evaluates the PA status of drugs on an ongoing basis. Drugs and biologics may be added to this Part as appropriate and updated on the MHDL accordingly.

FDA-Approved New-to-Market Drugs

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 an FDA-approved new-to-market drug or biologic not listed in the MHDL is an "APAD Carve-Out Drug" for purposes of the Acute Hospital RFA (or MassHealth regulations, as applicable) and this Part I.

II. APEC Carve-Out Drugs (administered in an *acute outpatient hospital* setting)

The drugs and biologics listed in this Part II are "**APEC Carve-Out Drugs**" for purposes of Section 5.C.9 of the Acute Hospital RFA, and MassHealth regulations at 130 CMR 450.233(D). The APEC Carve-Out Drugs will be listed alphabetically by therapeutic class, then by the name of the drug or drug ingredients.

Please note that, in addition to PA and other requirements, these therapies require both short- and long-term monitoring for efficacy and durability of response. MassHealth will be conducting outreach to prescriber's offices to gather the applicable information.

CAR-T Therapies

See Therapeutic Class Table 75 on the MassHealth Drug List for additional information on CAR-T Therapies, including approval criteria and monitoring parameters

- Kymriah (tisagenlecleucel) – **PA****
  *** Please note that PA approval will require a letter from the hospital's financial department addressing participation status in the manufacturer's outcomes-based contract.*
- Tecartus (brexucabtagene autoleucel) – **PA**
- Yescarta (axicabtagene ciloleucel) – **PA**

Process: Prescriber must submit a request for PA for the CAR-T therapy to MassHealth using the Chimeric Antigen Receptor (CAR)-T Immunotherapies Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved. MassHealth will conduct ongoing monitoring of the treatment, based on parameters including: dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; and response to therapy (e.g., complete blood count, bone marrow blasts, peripheral blood blasts, platelets, absolute neutrophil counts). See MassHealth Chimeric Antigen Receptor (CAR)-T Immunotherapies Monitoring Program document on the MassHealth Drug List for additional information.

Inherited Retinal Disease Gene Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Luxturna, including approval criteria and monitoring parameters

- Luxturna (voretigene neparvovec) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Luxturna Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved. MassHealth will then conduct ongoing monitoring of the treatment, based on parameters that may include: dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; and response to therapy (e.g., full-field light sensitivity threshold [FST] scores). See MassHealth Luxturna Monitoring Program document on the MassHealth Drug List for additional information.

Spinal Muscular Atrophy Gene Therapy

See Therapeutic Class Table 76 on the MassHealth Drug List for additional information on Zolgensma, including approval criteria and monitoring parameters

- Zolgensma (onasemnogene abeparvovec-xioi) – **PA**

Process: Prescriber must submit a request for PA using the Neuromuscular Agents Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved. MassHealth will conduct ongoing monitoring of the treatment, based on parameters that may include: dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; and response to therapy (e.g., updates of clinically appropriate motor function tests). See MassHealth Zolgensma Monitoring Program document on the MassHealth Drug List for additional information.

MassHealth evaluates the PA status of drugs on an ongoing basis. Drugs and biologics will be added to this Part as appropriate and updated on the MHDL accordingly.

FDA-Approved New-to-Market Drugs

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 an FDA-approved new-to-market drug or biologic not listed in the MHDL is an “APEC Carve-Out Drug” for purposes of the Acute Hospital RFA (or MassHealth regulations, as applicable) and this Part II.