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.

Anti-Hemophilia Gene Therapy

See Therapeutic Class Table 80 on the MassHealth Drug List for additional information on Roctavian, including approval criteria and monitoring parameters.

- Roctavian (valoctocogene roxaparvovec-fox) – PA
**Process:** Prescriber must submit a request for PA to MassHealth using the [Hemophilia A and B 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.

**Beta Thalassemia Gene Therapy**

See [Therapeutic Class Table 45 on the MassHealth Drug List for additional information on Zynteglo](#), including approval criteria and monitoring parameters.

- Zynteglo (betibeglogene autotemcel) – PA

**Process:** Prescriber must submit a request for PA to MassHealth using the [Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease 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.

**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.

- Abecma (idecabtagene vicelucel) – PA
- Breyanzi (lisocabtagene maraleucel) – PA
- Carvykti (cilucabtagene autoleucel) – PA
- 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.

**Cerebral Adrenoleukodystrophy Gene Therapy**

See [Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Skysona](#), including approval criteria and monitoring parameters.

- Skysona (elivaldogene autotemcel) – PA

**Process:** Prescriber must submit a request for PA to MassHealth using the [Skysona 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.

**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.

**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 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.

**Anti-Hemophilia Gene Therapy**

See Therapeutic Class Table 80 on the MassHealth Drug List for additional information on Roctavian, including approval criteria and monitoring parameters.

- Roctavian (valoctocogene roxaparvovec-rvox) – PA
**Process:** Prescriber must submit a request for PA to MassHealth using the [Hemophilia A and B Prior Authorization Request form](#). The prescriber will be notified via fax if the PA request has been approved.

**Beta Thalassemia Gene Therapy**

See Therapeutic Class Table 45 on the MassHealth Drug List for additional information on Zynteglo, including approval criteria and monitoring parameters.

- Zynteglo (betibeglogene autotemcel) – PA

**Process:** Prescriber must submit a request for PA to MassHealth using the [Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request form](#). The prescriber will be notified via fax if the PA request has been approved.

**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.

- Abecma (idecabtagene vicleucel) – PA
- Breyanzi (lisocabtagene maraleucel) – PA
- Carvykti (ciltaclabtagene autoleucel) – PA
- 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.

**Cerebral Adrenoleukodystrophy Gene Therapy**

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

- Skysona (elivaldogene autotemcel) – PA

**Process:** Prescriber must submit a request for PA to MassHealth using the [Skysona Prior Authorization Request form](#). The prescriber will be notified via fax if the PA request has been approved.

**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 neaparvovec) – 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.

**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 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**

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