

Select High Cost, Orphan, and Accelerated Approval Drugs

This data table provides interim coverage information for a list of select drugs, including high cost drugs, orphan drugs, and other drugs approved under a Food and Drug Administration (FDA) accelerated approval pathway. These drugs are covered for FDA-approved indications when medically necessary. Information about a drug’s FDA-approved indication(s) can be found on the FDA website. Specific interim billing and coverage information for each drug can be found in the table below. These drugs and the billing or coverage of ancillary services related to these drugs are subject to all existing ForwardHealth coverage and billing policy, which may be found in the [ForwardHealth Online Handbook](#) on the ForwardHealth Portal.

If a drug listed below has established drug-specific clinical criteria, refer to the [Services Requiring Prior Authorization](#) chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook on the Portal for information about the clinical criteria and directions for submitting prior authorization (PA) requests.

If a drug listed below requires PA to support that use is for an FDA-approved indication and is medically necessary as defined by Wis. Admin. Code § DHS 101.03(96m) but does not have drug-specific clinical criteria, PA requests must be submitted using Section VII (Clinical Information for Other Drug Requests) of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016), and the Prior Authorization Request Form (PA/RF), F-11018 (05/13). Medical records (e.g., chart notes, laboratory values) must be submitted along with the PA request to support that use is both medically necessary and for an FDA-approved indication. The drug must be prescribed in a dose and manner consistent with FDA-approved product labeling.

For specific questions about the billing or coverage of high cost, orphan, and accelerated approval drugs listed in this data table, providers may contact Provider Services at 800-947-9627 or email DHSOrphanDrugs@dhs.wisconsin.gov.

Note: The information contained in this data table is subject to change, and it is the provider’s responsibility to remain up-to-date with the information included in this data table.

Effective: 04/01/2024

ABECMA idecabtagene	<ul style="list-style-type: none">○ Abecma does not require PA.○ Abecma will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., NCCN guidelines).○ Abecma will be covered under the pharmacy benefit.○ To bill ForwardHealth for Abecma, pharmacy providers should submit a pharmacy noncompound drug claim.
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<p>AMONDYS 45 casimersen</p>	<ul style="list-style-type: none"> ○ Amondys 45 requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Amondys 45 is approved, Amondys 45 will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Amondys 45, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>BREYANZI lisocabtagene maraleucel</p>	<ul style="list-style-type: none"> ○ Breyanzi does not require PA. ○ Breyanzi will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines). ○ Breyanzi will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Breyanzi, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>BRINEURA cerliponase</p>	<ul style="list-style-type: none"> ○ Brineura does not require PA. ○ Brineura will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines). ○ Brineura will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Brineura, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>CARVYKTI ciltacabtagene</p>	<ul style="list-style-type: none"> ○ Carvykti does not require PA. ○ Carvykti will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines). ○ Carvykti will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Carvykti, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>CEREZYME imiglucerase</p>	<ul style="list-style-type: none"> ○ Cerezyme does not require PA. ○ Cerezyme will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines). ○ Cerezyme will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Cerezyme, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>CRYSVITA burosumab-twza</p>	<ul style="list-style-type: none"> ○ Crysvita requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Crysvita is approved, Crysvita will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Crysvita, pharmacy providers should submit a pharmacy noncompound drug claim.

<p>ELAPRASE idursulfase</p>	<ul style="list-style-type: none"> ○ Elaprase does not require PA. ○ Elaprase will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., NCCN guidelines). ○ Elaprase will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Elaprase, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>ELEVIDYS delandistrogene moxeparvovec-rokl</p>	<ul style="list-style-type: none"> ○ Elevidys requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Elevidys is approved, Elevidys will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Elevidys, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>EXONDYS 51 eteplirsen</p>	<ul style="list-style-type: none"> ○ Exondys 51 requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Exondys 51 is approved, Exondys 51 will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Exondys 51, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>GAMIFANT emapalumab-lzsg</p>	<ul style="list-style-type: none"> ○ Gamifant requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Gamifant is approved, Gamifant will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Gamifant, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>HEMGENIX etranacogene dezaparvovec - drlb</p>	<ul style="list-style-type: none"> ○ Hemgenix requires PA ; established clinical criteria for Hemgenix can be found in the Online Handbook on the Portal.. ○ If a PA request for Hemgenix is approved, Hemgenix will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Hemgenix, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>KYMRIAH tisagenlecleucel</p>	<ul style="list-style-type: none"> ○ Kymriah does not require PA. ○ Kymriah will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., NCCN guidelines). ○ Kymriah will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Kymriah, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>LUXTURNA voretigene neparvovec- rzyl</p>	<ul style="list-style-type: none"> ○ Luxturna requires PA; established clinical criteria for Luxturna can be found in the Online Handbook on the Portal. ○ If a PA request for Luxturna is approved, Luxturna will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Luxturna, pharmacy providers should submit a pharmacy noncompound drug claim.

<p>MEPSEVII vestronidase alfa-vjvk</p>	<ul style="list-style-type: none"> ○ Mepsevii requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Mepsevii is approved, Mepsevii will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Mepsevii, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>ONPATTRO patisiran</p>	<ul style="list-style-type: none"> ○ Onpattro does not require PA. ○ Onpattro will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines). ○ Onpattro will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Onpattro, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>OXERVATE cenegermin</p>	<ul style="list-style-type: none"> ○ Oxervate does not require PA. ○ Oxervate will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines). ○ Oxervate will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Oxervate, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>ROCTAVIAN valoctocogene roxaparvovec-rvox</p>	<ul style="list-style-type: none"> ○ Roctavian requires PA ; established clinical criteria for Roctavian can be found in the Online Handbook on the Portal.. ○ If a PA request for Roctavian is approved, Roctavian will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Roctavian, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>RUZURGI amifampridine</p>	<ul style="list-style-type: none"> ○ Ruzurgi requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Ruzurgi is approved, Ruzurgi will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Ruzurgi, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>SKYSONA elivaldogene</p>	<ul style="list-style-type: none"> ○ Skysona requires PA to support that use is for an FDA- approved indication and is medically necessary. ○ A PA/DGA form Section VII must be submitted with the following clinical documentation and medical records to support the member's medical condition and outline the member's current treatment plan. <ul style="list-style-type: none"> ● Skysona must be prescribed by a physician with expertise in treating early, active cerebral adrenoleukodystrophy (CALD) at a minimum recommended dose of 5.0×10^6 CD34+ cells/kg. ● The member has early, active CALD, not due to head trauma. <ul style="list-style-type: none"> ○ Early, active CALD is defined as asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who

have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9.

- Skysona is only indicated for use in boys.
 - The member's age is consistent with the FDA-approved product labeling for Skysona.
 - The member will undergo hematopoietic stem cell (HSC) mobilization, apheresis, and myeloablative conditioning. The prescriber must confirm the member has been evaluated for renal and hepatic impairment and HSC transplantation is appropriate for the member.
 - The member must have full myeloablative and lymphodepleting conditioning administered before infusion of Skysona. Allow a minimum of 48 hours of washout before Skysona infusion.
 - The prescriber will complete screening for infectious diseases including hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines before collection of cells for manufacturing.
 - Standard procedures for patient management after HSC transplantation should be followed after Skysona infusion.
 - The prescriber must manage other concomitant medications (as applicable) consistent with FDA product labeling.
 - The member must not take anti-retroviral medications for at least one month prior to stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are complete.
 - If a member requires anti-retroviral medications for HIV prophylaxis, mobilization and apheresis should be delayed until HIV infection is adequately ruled out.
 - o If a PA request for Skysona is approved, Skysona will be covered under the pharmacy benefit.
 - o To bill ForwardHealth for Skysona, pharmacy providers should submit a pharmacy noncompound drug claim.
 - o Skysona will be reimbursed separately from physician and clinical services associated with the administration of Skysona. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that the physician-administered Skysona is delivered directly to the prescriber or an agent of the prescriber. Pharmacy providers may only submit a claim to ForwardHealth for the Skysona that has been administered to a member. If Skysona has been dispensed for a member but the dose is not administered to the member, the prescriber is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Skysona that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
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<p>SPINRAZA nusinersen</p>	<ul style="list-style-type: none"> ○ Spinraza requires PA; established clinical criteria for Spinraza can be found in the Online Handbook on the Portal. ○ If a PA request for Spinraza is approved, Spinraza will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Spinraza, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>TECARTUS brexucabtagene</p>	<ul style="list-style-type: none"> ○ Tecartus does not require PA. ○ Tecartus will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., NCCN guidelines). ○ Tecartus will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Tecartus, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>VILTEPSO viltolarsen</p>	<ul style="list-style-type: none"> ○ Viltepso requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Viltepso is approved, Viltepso will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Viltepso, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>VIMIZIM elosulfase alfa</p>	<ul style="list-style-type: none"> ○ Vimizim does not require PA. ○ Vimizim will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., NCCN guidelines). ○ Vimizim will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Vimizim, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>VYJUVEK beremagene geperpavec-svdt</p>	<ul style="list-style-type: none"> ○ Vyjuvek requires PA ; established clinical criteria for Vyjuvek can be found in the Online Handbook on the Portal. ○ If a PA request for Vyjuvek is approved, Vyjuvek will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Vyjuvek, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>VYONDYS 53 golodirsen</p>	<ul style="list-style-type: none"> ○ Vyondys 53 requires PA to support that use is for an FDA-approved indication and is medically necessary. ○ If a PA request for Vyondys 53 is approved, Vyondys 53 will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Vyondys 53, pharmacy providers should submit a pharmacy noncompound drug claim.

<p>YESCARTA axicabtagene ciloleucel</p>	<ul style="list-style-type: none"> ○ Yescarta does not require PA. ○ Yescarta will only be reimbursed when used for an FDA-approved indication and where use is appropriate with regard to generally accepted standards of medical practice (i.e., consistent with relevant professional society guidelines; e.g., NCCN guidelines). ○ Yescarta will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Yescarta, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>ZOLGENSMA onasemnogene abeparvovec-xioi</p>	<ul style="list-style-type: none"> ○ Zolgensma requires PA; established clinical criteria for Zolgensma can be found in the Online Handbook on the Portal. ○ If a PA request for Zolgensma is approved, Zolgensma will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Zolgensma, pharmacy providers should submit a pharmacy noncompound drug claim.
<p>ZYNTEGLO betibeglogene</p>	<ul style="list-style-type: none"> ○ Zynteglo requires PA to support that use is for an FDA- approved indication and is medically necessary. ○ A PA/DGA form Section VII must be submitted with the following clinical documentation and medical records to support the member's medical condition and outline the member's current treatment plan. <ul style="list-style-type: none"> ● Zynteglo must be prescribed by a physician with expertise in treating β-thalassemia at a minimum recommended dose of 5.0×10^6 CD34+ cells/kg of body weight. ● The member has β-thalassemia which requires regular red blood cell (RBC) transfusions. The member has a history of transfusions for the past 2 years of at least 100mL/kg/year of packed RBCs or with 8 or more transfusions of packed RBCs per year. ● The member's age is consistent with the FDA-approved product labeling for Zynteglo. ● The member will undergo hematopoietic stem cell (HSC) mobilization, apheresis, and myeloablative conditioning. The prescriber must confirm the member has been evaluated for renal and hepatic impairment and HSC transplantation is appropriate for the member. ● The member must have full myeloablative conditioning administered before infusion of Zynteglo. Allow a minimum of 48 hours of washout before Zynteglo infusion. ● The prescriber will complete screening for infectious diseases including hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines before collection of cells for manufacturing. ● Standard procedures for patient management after HSC transplantation should be followed after Zynteglo infusion. ● The prescriber must manage other concomitant medications (as applicable) consistent with FDA product labeling.

	<ul style="list-style-type: none"> • The member must not take anti-retroviral medications or hydroxyurea for at least one month prior to mobilization, or for the expected duration for elimination of the medications, and until all cycles of apheresis are completed. • If a member requires anti-retroviral medications for HIV prophylaxis, mobilization and apheresis should be delayed until HIV infection is adequately ruled out. • The member must stop iron chelation at least 7 days prior to myeloablative conditioning. The member will not use myelosuppressive iron chelators for at least 6 months after Zynteglo infusion. <ul style="list-style-type: none"> ○ If a PA request for Zynteglo is approved, Zynteglo will be covered under the pharmacy benefit. ○ To bill ForwardHealth for Zynteglo, pharmacy providers should submit a pharmacy noncompound drug claim. ○ Zynteglo will be reimbursed separately from physician and clinical services associated with the administration of Zynteglo. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that the physician-administered Zynteglo is delivered directly to the prescriber or an agent of the prescriber. Pharmacy providers may only submit a claim to ForwardHealth for the Zynteglo that has been administered to a member. If Zynteglo has been dispensed for a member but the dose is not administered to the member, the prescriber is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Zynteglo that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
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Note: Pharmacy providers who receive Medicaid reimbursement for select high cost, orphan, and accelerated approval drugs may be subject to audit at any time. Pharmacy providers are required to retain relevant documentation supporting adherence to ForwardHealth program requirements and produce it for and/or submit it to ForwardHealth upon request. ForwardHealth may deny or recoup payment for services that fail to meet program requirements.