## 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 <u>Services</u> <u>Requiring Prior Authorization</u> 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 <u>DHSOrphanDrugs@dhs.wisconsin.gov</u>.

*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: 01/01/2024

ABECMA	• Abecma does not require PA.
idecabtagene	<ul> <li>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).</li> <li>Abecma will be covered under the pharmacy benefit.</li> <li>To bill ForwardHealth for Abecma, pharmacy providers should</li> </ul>
	submit a pharmacy noncompound drug claim.

AMONDYS 45	• Amondys 45 requires PA to support that use is for an FDA-approved
casimersen	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.
BREYANZI	• Breyanzi does not require PA.
lisocabtagene	• Breyanzi will only be reimbursed when used for an FDA-approved
maraleucel	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.
BRINEURA	• Brineura does not require PA.
cerliponase	• Brineura will only be reimbursed when used for an FDA-approved
	$\circ$ indication and where use is appropriate with regard to generally
	$\circ$ accepted standards of medical practice (i.e., consistent with relevant
	<ul> <li>professional society guidelines).</li> </ul>
	• Brineura will be covered under the pharmacy benefit.
	• To bill ForwardHealth for Brineura, pharmacy providers should
	$\circ$ submit a pharmacy noncompound drug claim.
CARVYKTI	• Carvykti does not require PA.
ciltacabtagene	• 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.
CEREZYME	• Cerezyme does not require PA.
imiglucerase	• 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.
CRYSVITA	• Crysvita requires PA to support that use is for an FDA-approved
burosumab-twza	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
	<ul> <li>To bill ForwardHealth for Crysvita, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>

ELAPRASE	a Elemnasa daga nat raguira DA
idursulfase	<ul> <li>Elaprase does not require PA.</li> <li>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).</li> </ul>
	<ul> <li>Elaprase will be covered under the pharmacy benefit.</li> </ul>
	<ul> <li>To bill ForwardHealth for Elaprase, pharmacy providers should</li> </ul>
	submit a pharmacy noncompound drug claim.
ELEVIDYS	• Elevidys requires PA to support that use is for an FDA-approved
delandistrogene	indication and is medically necessary.
moxeparvovec-rokl	• 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.
EXONDYS 51	• Exondys 51 requires PA to support that use is for an FDA-approved
eteplirsen	indication and is medically necessary.
	• If a PA request for Exondys 51 is approved, Exondys 51 will be
	covered under the pharmacy benefit.
	<ul> <li>To bill ForwardHealth for Exondys 51, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>
GAMIFANT	
emapalumab-lzsg	• Gamifant requires PA to support that use is for an FDA-approved indication and is medically necessary.
emapatuma0-128g	<ul> <li>If a PA request for Gamifant is approved, Gamifant will be covered</li> </ul>
	under the pharmacy benefit.
	• To bill ForwardHealth for Gamifant, pharmacy providers should
	submit a pharmacy noncompound drug claim.
HEMGENIX	• Hemgenix requires PA ; established clinical criteria for
etranacogene	Hemgenix can be found in the Online Handbook on the Portal
dezaparvovec - drlb	• 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.
KYMRIAH	• Kymriah does not require PA.
tisagenlecleucel	• 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.
LUXTURNA	• Luxturna requires PA; established clinical criteria for Luxturna can
voretigene	be found in the Online Handbook on the Portal.
neparvovec- rzyl	• If a PA request for Luxturna is approved, Luxturna will be covered under the pharmacy benefit
	<ul> <li>under the pharmacy benefit.</li> <li>To bill ForwardHealth for Luxturna, pharmacy providers should</li> </ul>
	<ul> <li>To bill ForwardHealth for Luxturna, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>
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MEPSEVII	-	Mangavii maning DA to support that use is for an EDA approved
vestronidase alfa-vjbk	0	Mepsevii requires PA to support that use is for an FDA-approved indication and is medically necessary.
vesuoniuase ana-vjok		If a PA request for Mepsevii is approved, Mepsevii will be covered
	0	under the pharmacy benefit.
	0	To bill ForwardHealth for Mepsevii, pharmacy providers should
	Ŭ	submit a pharmacy noncompound drug claim.
ONPATTRO	0	Onpattro does not require PA.
patisiran	0	Onpattro will only be reimbursed when used for an FDA-approved
pational	Ŭ	indication and where use is appropriate with regard to generally
		accepted standards of medical practice (i.e., consistent with relevant
		professional society guidelines).
	0	Onpattro will be covered under the pharmacy benefit.
	0	To bill ForwardHealth for Onpattro, pharmacy providers should
		submit a pharmacy noncompound drug claim.
OXERVATE	0	Oxervate does not require PA.
cenegermin	0	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).
	0	Oxervate will be covered under the pharmacy benefit.
	0	To bill ForwardHealth for Oxervate, pharmacy providers should
		submit a pharmacy noncompound drug claim.
ROCTAVIAN	0	Roctavian requires PA ; established clinical criteria for
valoctocogene		Roctavian can be found in the Online Handbook on the Portal
roxaparvovec-rvox	0	If a PA request for Roctavian is approved, Roctavian will be
		covered under the pharmacy benefit.
	0	To bill ForwardHealth for Roctavian, pharmacy providers should
		submit a pharmacy noncompound drug claim.
RUZURGI	0	Ruzurgi requires PA to support that use is for an FDA-approved
amifampridine		indication and is medically necessary.
	0	If a PA request for Ruzurgi is approved, Ruzurgi will be covered
	-	under the pharmacy benefit.
	0	To bill ForwardHealth for Ruzurgi, pharmacy providers should submit a pharmacy noncompound drug claim.
SPINRAZA	0	Spinraza requires PA; established clinical criteria for Spinraza can
nusinersen		be found in the Online Handbook on the Portal.
	0	If a PA request for Spinraza is approved, Spinraza will be covered under the pharmacy benefit.
		To bill ForwardHealth for Spinraza, pharmacy providers should
	0	submit a pharmacy noncompound drug claim.
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TECARTUS	• Tecartus does not require PA.
brexucabtagene	<ul> <li>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).</li> <li>Tecartus will be covered under the pharmacy benefit.</li> <li>To bill ForwardHealth for Tecartus, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>
VILTEPSO	• Viltepso requires PA to support that use is for an FDA-approved
viltolarsen	<ul> <li>indication and is medically necessary.</li> <li>If a PA request for Viltepso is approved, Viltepso will be covered under the pharmacy benefit.</li> <li>To bill ForwardHealth for Viltepso, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>
VIMIZIM	• Vimizim does not require PA.
elosulfase alfa	<ul> <li>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).</li> <li>Vimizim will be covered under the pharmacy benefit.</li> <li>To bill ForwardHealth for Vimizim, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>
VYJUVEK	• Vyjuvek requires PA ; established clinical criteria for Vyjuvek can be
beremagene	found in the Online Handbook on the Portal.
geperpavec-svdt	• If a PA request for Vyjuvek is approved, Vyjuvek will be covered under the pharmacy benefit.
	<ul> <li>To bill ForwardHealth for Vyjuvek, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>
VYONDYS 53	• Vyondys 53 requires PA to support that use is for an FDA-approved
golodirsen	<ul> <li>indication and is medically necessary.</li> <li>If a PA request for Vyondys 53 is approved, Vyondys 53 will be</li> </ul>
	covered under the pharmacy benefit.
	• To bill ForwardHealth for Vyondys 53, pharmacy providers should submit a pharmacy noncompound drug claim.
YESCARTA	• Yescarta does not require PA.
axicabtagene ciloleucel	• 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)
	<ul> <li>professional society guidelines; e.g., NCCN guidelines).</li> <li>Yescarta will be covered under the pharmacy benefit.</li> <li>To bill ForwardHealth for Yescarta, pharmacy providers should submit a pharmacy noncompound drug claim.</li> </ul>

0	Zolgensma requires PA; established clinical criteria for Zolgensma
	can be found in the Online Handbook on the Portal.
0	If a PA request for Zolgensma is approved, Zolgensma will be
	covered under the pharmacy benefit.
0	To bill ForwardHealth for Zolgensma, pharmacy providers should
	submit a pharmacy noncompound drug claim.
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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.