

RECENT FDA-APPROVED MEDICAL DRUGS or MEDICAL DRUG INDICATIONS EVALUATION PROCESS LIST



Updated: May 8, 2024

As new drugs and/or drug indications are approved by the Food and Drug Administration (FDA) for use in the United States (US), Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) carefully examines the scientific evidence and outcomes of new drug treatments. During this process, Blue Cross may decide a new medical drug requires further evaluation to determine appropriate coverage or utilization management drug policies for medical drug benefits. Medical drugs are generally administered by infusion or injection by a healthcare professional and process under the medical benefit.

Medical Drug Evaluation Process

As new to market medical drugs are evaluated, Blue Cross's **Medical Drug Evaluation Process** involves clinical review of recent FDA-approved medical drugs or medical drug indications within 6 months of FDA approval. Blue Cross's Medical Policy Committee carefully examines the scientific evidence and outcomes for each medical drug treatment under consideration. The clinical review includes evaluation of published data and evidence supporting the safety, effectiveness, and the effect of the drug on health outcomes. The Medical Policy Committee's goal is to find the right balance between making new treatments available and guarding against unsafe or unproven approaches.

While new medical drugs and/or drug indications are under clinical review, the treatment is considered *experimental/investigative* until the evaluation process is completed, and a determination made if the treatment should be a covered service under the medical benefit. Covered services are determined in accordance with Blue Cross' policies in effect at the time treatment is rendered. Claims submitted while a drug is under review are subject to retrospective review and may be denied.

The following recently FDA-approved drugs are under clinical review by Blue Cross upon FDA approval, per medical policy II-174:

Drug Generic Name (Brand Name)	Date Drug Added to List	FDA Approval	Date Drug Removed from List	Resolution / List History
<i>Crovalimab</i>	5.8.2024			<i>Medical Policy II-174 will apply upon FDA drug approval.</i>
<i>Fidanacogene eleparvovec (Beqvez)</i>	5.8.2024	4.25.2024		<i>Medical Policy II-174 will apply upon FDA drug approval.</i>
<i>Atidarsagene autotemcel (Lenmeldy)</i>	5.8.2024	3.18.2024		<i>Medical Policy II-174 will apply upon FDA drug approval.</i>
<i>Marnetegrage autotemcel (Kresladi)</i>	4.10.2024			<i>Medical Policy II-174 will apply upon FDA drug approval.</i>
<i>Prademagene zamikeracel</i>	4.10.2024			<i>Medical Policy II-174 will apply upon FDA drug approval.</i>
<i>Donanemab</i>	3.1.2024			<i>Medical Policy II-174 will apply upon FDA drug approval.</i>
<i>Exagamglogene autotemcel (Casgevy)</i>	12.14.2024	12.8.2023	6.3.2024	<i>Medical Policy II-174 applies 12.8.2023 to 6.2.2024, then policy II-II-293 will apply.</i>
<i>Lovotibeglogene autotemcel (Lyfgenia)</i>	12.14.2024	12.8.2023	6.3.2024	<i>Medical Policy II-174 applies 12.8.2023 to 6.2.2024, then policy II-294 will apply.</i>
<i>Infliximab-dyyb for SC use (Zymfentra)</i>	12.1.2023	10.23.2023	4.1.2024	<i>Medical Policy II-174 will apply upon FDA drug approval; then policy II-173 will apply.</i>
<i>Epcoritamab (Epkiny)</i>	5.24.2023	5.19.2023	11.6.2023	<i>Medical Policy II-174 applies 5.19.2023 to 11.5.2023, then policy II-283 will apply.</i>
<i>Delandistrogene moxeparvovec (Elevidys)</i>	5.24.2023	6.22.2023	12.4.2023	<i>Medical Policy II-174 applies 6.22.2023 to 12.3.2023, then policy II-284 will apply.</i>
<i>Tofersen (Qalsody)</i>	4.12.2023	4.25.2023	10.2.2023	<i>Medical Policy II-174 applies 4.25.2023 to 10.1.2023, then policy II-281 will apply.</i>
<i>Lecanemab (Leqembi)</i>	12.14.2022	1.6.2023	6.5.2023	<i>Medical Policy II-174 applies 1.6.2023 to 6.4.2023, then policy II-276 will apply.</i>

Drug Generic Name (Brand Name)	Date Drug Added to List	FDA Approval	Date Drug Removed from List	Resolution / List History
<i>Lifileucil (Amtagvi)</i>	12.14.2022	2.16.2024		<i>Medical Policy II-174 will apply upon FDA drug approval</i>
<i>Etranacogene dezaparvovec (Hemgenix)</i>	11.23.2022	11.22.2022	7.3.2023	<i>Medical Policy II-174 applies 11.22.2022 to 7.2.2023, then policy II-273 will apply.</i>
<i>Betibeglogene autotemcel (Zynteglo)</i>	6.17.2022	8.17.2022	1.2.2023	<i>Medical Policy II-174 applies 8.17.2022 to 1.1.2023, then policy II-267 will apply.</i>
<i>Vutrisiran (Amvuttra)</i>	12.8.2021	6.13.2022	10.31.2022	<i>Medical Policy II-174 applies 6.13.2022 to 10.30.22, then policy II-264 will apply.</i>
<i>Triamcinolone acetonide injectable (Xipere)</i>	12.8.2021	10.25.2021	5.2.2022	<i>Medical Policy II-174 applies 12.8.2021 to 5.1.2022, then policy II-257 will apply.</i>
<i>Tezepelumab (Tezspire)</i>	11.10.2021	12.17.2021	6.6.2022	<i>Medical Policy II-174 applies 12.17.2021 to 6.5.2022, then policy II-259 will apply.</i>
<i>Faricimab (Vabysmo)</i>	11.10.2021	1.28.2022	7.4.2022	<i>Medical Policy II-174 applies 1.28.2022 to 7.3.2022, then policy II-71 will apply.</i>
<i>Ranibizumab Injection (Susvimo)</i>	11.10.2021	10.23.2021	4.4.2022	<i>Medical Policy II-174 applies 10.23.2021 to 4.3.2022, then policy II-71 will apply.</i>
<i>Ciltacabtagene autoleucl (Carvykti)</i>	9.8.2021	2.28.2022	8.1.2022	<i>Medical Policy II-174 applies 2.28.2022 to 7.31.2022, then policy II-262 will apply.</i>
<i>Anifrolumab (Saphnelo)</i>	6.9.2021	7.30.2021	1.3.2022	<i>Medical Policy II-174 applies 7.30.2021 to 1.2.2022, then policy II-255 will apply.</i>
<i>Teplizumab (Tziel)</i>	6.9.2021	11.17.2022	5.1.2023	<i>Medical Policy II-174 applies 11.17.2022 to 4.30.2023, then policy II-272 will apply.</i>
<i>Donislecel (Lantidra)</i>	6.9.2021	6.28.2023	12.4.2023	<i>Medical Policy II-174 applies 6.28.2023 to 12.3.2023, then policy IV-09 will apply.</i>
<i>Difelikefalin (Korsuva)</i>	6.9.2021	8.23.2021	2.1.2022	<i>Medical Policy II-174 applies 8.23.2021 to 2.1.2022, then policy II-173 will apply.</i>
<i>Avalglucosidase alfa (Nexviazyme)</i>	4.14.2021	8.6.2021	1.31.2022	<i>Medical Policy II-174 applies 8.6.2021 to 1.30.2022, then policy II-256 will apply.</i>
<i>Selezipag injection (Uptravi IV)</i>	4.14.2021	7.30.2021	1.30.2022	<i>Medical Policy II-174 applies 8.6.2021 to 1.30.2022, then policy II-107 will apply.</i>
<i>Aducanumab (Aduhelm)</i>	1.13.2021	6.7.2021	12.6.2021	<i>Medical Policy II-174 applies 6.7.2021 to 12.5.2021, then policy II-253 & II-254 apply.</i>
<i>Casimersen (Amondys 45)</i>	1.13.2021	2.25.2021	8.2.2021	<i>Medical Policy II-174 applies 2.25.2021 to 8.1.2021, then policy II-251 will apply.</i>
<i>Evinacumab (Evkeeza)</i>	1.13.2021	2.11.2021	7.5.2021	<i>Medical Policy II-174 applies 2.11.2021 to 7.4.2021, then policy II-250 will apply.</i>
<i>Idcabtagene vicleucl (Abecma)</i>	1.13.2021	3.26.2021	8.30.2021	<i>Medical Policy II-174 applies 3.26.2021 to 8.29.2021, then policy II-252 will apply.</i>
<i>Pegunigalsidase alfa (Elfabrio)</i>	1.13.2021	5.9.2023	10.2.2023	<i>Medical Policy II-174 applies 5.9.2023 to 10.1.2023, then policy II-281 will apply.</i>
<i>Inclisiran (Leqvio)</i>	10.14.2020	12.22.2021	6.6.2022	<i>Medical Policy II-174 applies 12.22.2021 to 6.5.2022, then policy II-258 will apply.</i>
<i>Tanezumab</i>	9.9.2020	None	5.24.2023	<i>The drug was under review by FDA but was not approved.</i>
<i>Viltolarsen (Viltepso)</i>	7.15.2020	8.12.2020	1.4.2021	<i>Medical Policy II-174 applies 8.12.2020 to 1.3.2021, then policy II-246 will apply.</i>
<i>Valoctocogene roxaparvovec (Roctavian)</i>	5.13.2020	6.29.2023	12.4.2023	<i>Medical Policy II-174 applies 6.29.2023 to 12.3.2023, then policy II-286 will apply.</i>
<i>Teprotumumab-trbw (Tepezza)</i>	2.12.2020	1.21.2020	7.6.2020	<i>Medical Policy II-174 applies 2.12.2020 to 7.5.2020, then policy II-239 will apply.</i>
<i>Golodirsen (Vyondys 53)</i>	5.8.2019	12.13.2019	5.04.2020	<i>Medical Policy II-174 applies 1.08.2020 to 5.03.2020, then policy II-232 will apply.</i>
<i>Esketamine Nasal Spray (Spravato)</i>	1.23.2019	3.05.2019	4.01.2019	<i>Medical Policy II-174 applies 3.5.2019 to 3.31.2019; between 4.1.2019 and 6.30.2019 policy II-173 applies, after which policy II-226 will apply.</i>

**Blue Cross reserves the right to revise, update, or add/remove drugs to the list at any time without notice as new drugs are approved by the FDA and become available for use.*

Members Impacted

Subscribers with coverage through Commercial health plans, excluding Federal Employee Program (FEP).

Notes

- Providers are encouraged to review this list periodically for updates.
- Medical drugs do not include drugs that process under the pharmacy benefit, such as self-administered drugs or oral pills.

- The requirement of Committee review is a precondition of Blue Cross coverage and applies in addition to all other conditions and terms stated in Blue Cross contracts. For additional information on the Medical Drug Evaluation Process, **see Medical Policy II-174: New FDA-Approved Medical Drugs or Medical Drug Indications**. To access Blue Cross medical policies:
 - Go to providers.bluecrossmn.com
 - Under “Medical Management”, select “Medical and behavioral health policies”.
 - Select “Search Medical and Behavioral Health Policies” to view current policies.
 - Or select the “See upcoming medical and behavioral health policy notification” to see new policies going into effect.

Questions?

If you have questions, please contact provider services at **(651) 662-5200** or **1-800-262-0820**.