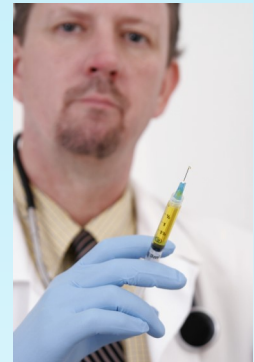


IHCP *bulletin*

INDIANA HEALTH COVERAGE PROGRAMS BT202110 FEBRUARY 16, 2021

IHCP clarifies drugs carved-out of managed care and PA criteria

The Indiana Health Coverage Programs (IHCP) is providing a summary of the drugs carved out of managed care pharmacy and medical benefits and where to find prior authorization (PA) criteria. As a reminder, carved-out drugs are processed through the fee-for-service (FFS) pharmacy and medical benefit for all IHCP members, including those in the Healthy Indiana Plan (HIP), Hoosier Care Connect, and Hoosier Healthwise programs administered by Anthem, CareSource, MDwise, Managed Health Services (MHS), and (effective April 1, 2021) UnitedHealthcare.



Pharmacy benefit claim submissions and PA requests are processed by the FFS pharmacy benefit manager (PBM), OptumRx. Except for PA requests for Zolgensma (see *IHCP Bulletin* [BT202084](#)), medical benefit professional claims and PA requests are processed by Gainwell Technologies.

Initially, drugs carved out from managed care benefits were limited to the hepatitis C treatment drugs (see *IHCP Bulletin* [BT201644](#)), but the list has broadened over time to include several classes of pharmacy-dispensed (see *IHCP Bulletin* [BT201810](#)) and physician-administered drugs (PADs) (see *IHCP Bulletin* [BT201812](#)). There are currently eight therapeutic classes of drugs that have been carved out of the managed care benefit (see Table 1).

Table 1 – Drug therapies carved out of the managed care benefit

Drug class	Examples		
Chimeric Antigen Receptor (CAR) T-Cell Gene Therapies ¹	Kymriah (tisagenlecleucel)	Tecartus (brexucabtagene)	Yescarta (axicabtagene)
Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Potentiator Agents ²	Kalydeco (ivacaftor) Orkambi (lumacaftor-ivacaftor)	Symdeko (tezacaftor-ivacaftor and ivacaftor pack)	Trikafta (elexacaftor-tezacaftor-ivacaftor and ivacaftor pack)
Gene Therapies for Retinal Dystrophy ¹	Luxturna (voretigene)		
Hemophilia Blood Coagulation Factors and Hemophilia Hemostatic Agents	Antihemophilic Factors/Concentrate Hemlibra (emicizumab) Factor IX Complex	Coagulation Factors Fibrinogen Concentrate Prothrombin Complex Human	Antiinhibitor Coagulant Complex Von Willebrand Factor Antihemophilic/Von Willebrand Factor Complex

¹ Claims reimbursed through the FFS medical benefit only

² Claims reimbursed through the FFS pharmacy benefit only

³ Hepatitis C agent claims reimbursed through the FFS pharmacy benefit only, except the ribavirins and peginterferons

Table 1 – Drug therapies carved out of the managed care benefit (Continued)

Drug class	Examples		
Hepatitis C Agents ³	Sovaldi (sofosbuvir)	Mavyret (glecaprevir-pibrentasvir)	Harvoni (ledipasvir-sofosbuvir)
	Vosevi (sofosbuvir-velpatasvir-voxilaprevir)	Ribavirin	Epclusa (sofosbuvir-velpatasvir)
	Zepatier (elbasvir-grazoprevir)	Peginterferon-alfa-2a Peginterferon-alfa-2b	Viekira Pak (ombitasparitaprevir-ritonavir & dasab pak)
Non-corticosteroid Muscular Dystrophy Agents	Exondys 51 (eteplirsen)	Viltepso ² (vitolareshen)	Vyondys 53 (golodirsen)
Non-hydroxyurea Sickle Cell Agents	Adakveo (crizanlizumab-tmca)		Oxbryta ² (voxelotor)
Spinal Muscular Atrophy (SMA) Agents	Spinraza (nusinersen)	Evrysdi ² (risdiplam)	Zolgensma ¹ (onasemnogene abeparvovec-xioi)

¹ Claims reimbursed through the FFS medical benefit only

² Claims reimbursed through the FFS pharmacy benefit only

³ Hepatitis C agent claims reimbursed through the FFS pharmacy benefit only, except the ribavirins and peginterferons

An up-to-date list of carved-out drugs can be found using the quick link, *Carved-out Drug Benefits*, on the OptumRx Indiana Medicaid website, accessible from the [Pharmacy Services](#) page at in.gov/medicaid/providers.

Carved-out drug prior authorization criteria

PA criteria are posted in the locations presented in Table 2.

Table 2 – Location of PA criteria for carved-out drugs

Drug class	PA criteria location
Chimeric Antigen Receptor (CAR) T-Cell Gene Therapy	PA criteria for physician-administered oncology drugs are listed in the Oncology Services provider reference module. New PA criteria for Tecartus and Yescarta, effective for claims with dates of service (DOS) on or after January 1, 2021, are listed in this bulletin in the CAR-T treatments section. Criteria for Kymriah remain unchanged.
Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Potentiator Agents	<i>Cystic Fibrosis Agents PA Criteria</i> are listed under Pharmacy Criteria and Forms in the Preferred Products drop-down menu on the OptumRx Indiana Medicaid website .
Gene Therapies for Retinal Dystrophy	PA criteria for physician-administered ophthalmologic drugs are listed in the Vision Services provider reference module.
Hemophilia Blood Coagulation Factors and Hemophilia Hemostatic Agents	None required.
Hepatitis C Agents	<i>Hepatitis C Agents PA Criteria</i> are listed under Pharmacy Criteria and Forms in the Preferred Products drop-down menu on the OptumRx Indiana Medicaid website .
Non-corticosteroid Muscular Dystrophy Agents	<i>Muscular Dystrophy Agents PA Criteria</i> are listed under Pharmacy Criteria and Forms in the Preferred Products drop-down menu on the OptumRx Indiana Medicaid website . Exondys 51 and Vyondys 53 PA criteria are listed in the Injections, Vaccines, and Other Physician-Administered Drugs provider reference module.

Table 2 – Location of PA criteria for carved-out drugs (Continued)

Drug class	PA criteria location
Non-hydroxyurea Sickle Cell Agents	<i>Sickle Cell Agents PA Criteria</i> are listed under Pharmacy Criteria and Forms in the Preferred Products drop down menu on the OptumRx Indiana Medicaid website .
Spinal Muscular Atrophy (SMA) Agents	<i>Spinal Muscular Atrophy Agents PA</i> are listed under Pharmacy Criteria and Forms in the Preferred Products drop down menu on the OptumRx Indiana Medicaid website . <i>Spinraza PA</i> criteria are listed in the Injections, Vaccines, and Other Physician-Administered Drugs provider reference module.

CAR-T treatments

The IHCP covers the chimeric antigen receptor T-cell (CAR-T) treatments (listed in this bulletin) with prior authorization. The PA criteria for the Tecartus and Yescarta treatments are effective for claims with DOS on or after January 1, 2021.

These treatments may be considered medically necessary when all the following criteria are met:

- Member has not previously received the specified CAR-T treatment.
- Member will be administered the specified CAR-T treatment:
 - At a facility that is Risk Evaluation and Mitigation Strategy (REMS) Program-certified for the specified CAR-T treatment
 - By healthcare providers that have successfully completed the specified CAR-T REMS Program Knowledge Assessment

Additional PA requirements include the following specific criteria for each treatment:

- For **tisagenlecleucel (Kymriah)**, the member is either:
 - 25 years of age or younger with a diagnosis of B-cell lymphoblastic leukemia that is refractory or in second or later relapse
 - At least 18 years of age with a diagnosis of relapsed or refractory large B-cell lymphoma following at least two lines of systemic therapy:
 - ◆ Including any of the following:
 - ⇒ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
 - ⇒ High-grade B-cell lymphoma
 - ⇒ DLBCL arising from follicular lymphoma
 - ◆ And does not have a diagnosis of primary central nervous system lymphoma

Kymriah is billed using Healthcare Common Procedure Coding System (HCPCS) code Q2042 – Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedure, per therapeutic dose.

- For **brexucabtagene autoleucl (Tecartus)**, the member is:
 - At least 18 years of age with a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

Effective for claims with DOS on or after January 1, 2021, Tecartus is billed using HCPCS code C9073 – Brexucabtagene autoleucl, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

- For **axicabtagene ciloleucl (Yescarta)**, the member is:
 - At least 18 years of age with a diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy:
 - ◆ Including any of the following:
 - ⇒ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
 - ⇒ Primary mediastinal large B-cell lymphoma
 - ⇒ High-grade B-cell lymphoma
 - ⇒ DLBCL arising from follicular lymphoma
 - ◆ And does not have a diagnosis of primary central nervous system lymphoma

Yescarta is billed using HCPCS code Q2041 – Axicabtagene ciloleucl, up to 200 million autologous anti-CD19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

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