INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

# Oncology Services

LIBRARY REFERENCE NUMBER: PROMOD00061
PUBLISHED: SEPT. 8, 2022
POLICIES AND PROCEDURES AS OF JULY 1, 2022
VERSION: 4.0

# Revision History

| Version | Date | Reason for Revisions | Completed By |
|---|---|---|---|
| 1.0 | Policies and procedures as of Nov. 1, 2018<br>Published: July 30, 2019 | New document | FSSA and DXC |
| 2.0 | Policies and procedures as of Feb. 1, 2020<br>Published: March 13, 2020 | Scheduled update | FSSA and DXC |
| 3.0 | Policies and procedures as of Feb. 1, 2021<br>Published: April 20, 2021 | Scheduled update | FSSA and Gainwell |
| 4.0 | Policies and procedures as of July 1, 2022<br>Published: Sept. 8, 2022 | Scheduled update:<br>• Reorganized and edited text as needed for clarity<br>• Updated the *Chemotherapy and Radiation as Outpatient Hospital Services* section<br>• Updated the *CAR-T Treatments* section<br>• Updated the *Axicabtagene Ciloleucel (Yescarta)* section<br>• Updated the *Brexucabtagene Autoleucel (Tecartus)* section<br>• Added the *Ciltacabtagene Autoleucel (Carvykti)* section<br>• Added the *Idecabtagene Vicleucel (Abecma)* section<br>• Added the *Lisocabtagene Maraleucel (Breyanzi)* section<br>• Updated the *Tisagenlecleucel (Kymriah)* section | FSSA and Gainwell |

# 1 Table of Contents

> *Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the **fee-for-service (FFS)** delivery system. For information about services provided through the **managed care** delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect or Hoosier Healthwise member services – providers must contact the member's managed care entity (MCE) or refer to the MCE provider manual. MCE contact information is included in the IHCP Quick Reference Guide available at in.gov/medicaid/providers.*
>
> *For updates to information in this module, see IHCP Banner Pages and Bulletins at in.gov/medicaid/providers.*

# Introduction

The Indiana Health Coverage Programs (IHCP) covers oncology services, including cancer prevention, diagnosis, therapeutic treatment, rehabilitation and palliative care, as described in this module.

For information about screening and evaluation for cancer, see the *Genetic Testing*, *Obstetrical and Gynecological Services*, *Laboratory Services* and *Radiology Services* modules.

For information about bone marrow and stem cell transplants, see the *Surgical Services* module.

For information about devices used in the treatment of cancer, see the *Durable and Medical Equipment and Supplies* module.

# Chemotherapy and Radiation as Outpatient Hospital Services

All outpatient hospital chemotherapy and radiation treatment services are billed on the institutional claim (*UB-04* claim form, IHCP Provider Healthcare Portal [Portal] institutional claim or 837I electronic transaction). When chemotherapy and radiation treatment services are rendered on the same day, all applicable components should be billed. See the *Outpatient Facility Services* module for more information.

> *Note: Prior authorization (PA) is required when chemotherapy services are provided by a home health agency. For more information about services provided by a home health agency, see the Home Health Services module.*

## *Brachytherapy Services in the Outpatient Setting*

The IHCP covers certain Healthcare Common Procedure Coding System (HCPCS) codes for brachytherapy services performed in an outpatient setting. These services are billed on an institutional outpatient claim, including outpatient crossover claims. These codes are **not** separately reimbursable on professional claims (*CMS-1500* claim form, Portal professional claim or 837P electronic transaction).

Information about code-specific coverage, revenue code linkages, PA and reimbursement is available on the Outpatient Fee Schedule, accessible from the *IHCP Fee Schedules* page at in.gov/medicaid/providers.

# Physician-Administered Oncology Drugs

The following sections provide coverage and limitations for certain physician-administered drugs related to oncology. For general information about billing and reimbursement for physician-administered drugs, see the *Injections, Vaccines and Other Physician-Administered Drugs* module.

> *Note: Providers are reminded that all PA requests for gene therapy must include a letter of medical necessity **and** supportive patient/clinical chart documents demonstrating member diagnosis requirements.*

## *CAR-T Treatments*

The IHCP covers the chimeric antigen receptor T-cell (CAR-T) treatments with prior authorization.

To be eligible for authorization, the member must meet the medical criteria for the CAR-T treatment as described in the following sections, and must not have previously received the specified CART-T treatment. Additionally, the treatment must be administered at a facility that is Risk Evaluation and Mitigation Strategy (REMS) Program-certified for the specified CAR-T treatment, and by healthcare providers that have successfully completed the specified CAR-T REMS Program Knowledge Assessment.

CAR-T treatments are carved out of managed care and covered under the FFS medical benefit for all IHCP members. Claims for the following CAR-T treatments cannot be processed through the managed care entities (MCEs) or the pharmacy benefit manager. When provided in an inpatient setting, CAR-T treatment is separately reimbursable from the inpatient DRG when billed as a professional claim using the applicable procedure codes as described in the following sections.

### Axicabtagene Ciloleucel (Yescarta)

The IHCP covers axicabtagene ciloleucel (Yescarta) with PA. Yescarta may be considered medically necessary when the member meets ***all*** the following criteria:

- Has not previously received the Yescarta treatment
- Will be administered the Yescarta treatment as follows:
  - At a Yescarta REMS Program-certified facility
  - By healthcare providers that have successfully completed the Yescarta REMS Program Knowledge Assessment
- Is at least 18 years of age
- Has one of the following, diagnoses after two or more lines of systemic therapy:
  - Relapsed or refractory follicular lymphoma (for dates of service on or after July 1, 2021)
  - Relapsed or refractory large B-cell lymphoma:
    - 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
    - Does not have a diagnosis of primary central nervous system lymphoma

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

## Brexucabtagene Autoleucel (Tecartus)

The IHCP covers brexucabtagene autoleucel (Tecartus) with PA. Tecartus may be considered medically necessary when the member meets ***all*** the following criteria:

- Has not previously received the Tecartus treatment
- Will be administered the Tecartus treatment as follows:
  - At a Tecartus REMS Program-certified facility
  - By healthcare providers that have successfully completed the Tecartus REMS Program Knowledge Assessment
- Is at least 18 years of age
- Has a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

Tecartus is billed using HCPCS code Q2053 – *Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose*.

## Ciltacabtagene Autoleucel (Carvykti)

For dates of service on or after July 1, 2022, the IHCP covers ciltacabtagene autoleucel (Carvykti) with PA. Carvykti may be considered medically necessary when the member meets ***all*** the following criteria:

- Has not received prior Carvykti treatment
- Will be administered Carvykti treatment as follows:
  - At an Carvykti REMS Program-certified facility
  - By healthcare providers that have successfully completed the Carvykti REMS Program Knowledge Assessment
- Is at least 18 years of age
- Has a diagnosis of relapsed or refractory multiple myeloma after four or more prior lines of therapy, including the following:
  - Immunomodulatory agent
  - Proteasome inhibitor
  - Anti-CD38 monoclonal antibody

Carvykti is billed using HCPCS code C9098 – *Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose*.

## Idecabtagene Vicleucel (Abecma)

For dates of service on or after Oct. 1, 2022, the IHCP covers idecabtagene vicleucel (Abecma) with PA. Abecma may be considered medically necessary when the member meets ***all*** the following criteria:

- Has not received prior Abecma treatment
- Will be administered Abecma treatment as follows:
  - At an Abecma REMS Program-certified facility
  - By healthcare providers that have successfully completed the Abecma REMS Program Knowledge Assessment
- Is at least 18 years of age

- Has a diagnosis of relapsed or refractory multiple myeloma after four or more prior lines of therapy, including the following:
  - Immunomodulatory agent
  - Proteasome inhibitor
  - Anti-CD38 monoclonal antibody

Abecma is billed using HCPCS code Q2055 – *Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose.*

> *Note: For dates of service from Oct. 1, 2021, through Dec. 31, 2021, Abecma was billed using HCPCS code C9081.*

## Lisocabtagene Maraleucel (Breyanzi)

For dates of service on or after July 1, 2021, the IHCP covers lisocabtagene maraleucel (Breyanzi), with PA. Breyanzi may be considered medically necessary when the member meets ***all*** the following criteria:

- Has not received prior Breyanzi treatment
- Will be administered Breyanzi treatment as follows:
  - At a Breyanzi REMS Program-certified facility
  - By healthcare providers that have successfully completed the Breyanzi REMS Program Knowledge Assessment
- Is at least 18 years of age
- Has a diagnosis of relapsed or refractory large B-cell lymphoma, including any of the following, after two or more lines of systemic therapy:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
    - Including DLBCL arising from indolent lymphoma
  - Primary mediastinal large B-cell lymphoma
  - High grade B-cell lymphoma
  - Follicular lymphoma grade 3B
- Does not have a diagnosis of primary central nervous system lymphoma

Breyanzi is billed using HCPCS code Q2054 – *Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose*.

> *Note: For dates of service from July 1, 2021, through Sept. 30, 2021, Breyanzi should be billed using HCPCS code C9076.*

## Tisagenlecleucel (Kymriah)

The IHCP covers tisagenlecleucel (Kymriah) with PA. Kymriah may be considered medically necessary when the member meets ***all*** the following criteria:

- Has not received prior Kymriah treatment
- Will be administered Kymriah treatment as follows:
  - At a Kymriah REMS Program-certified facility
  - By healthcare providers that have successfully completed the Kymriah REMS Program Knowledge Assessment

- Is either of the following:
  - 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 and has one of the following diagnoses after two or more lines of systemic therapy:
    - Relapsed or refractory follicular lymphoma (for dates of service on or after June 1, 2022)
    - Relapsed or refractory large B-cell lymphoma:
      - Including any of the following:
        - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
        - High-grade B-cell lymphoma
        - DLBCL arising from follicular lymphoma
      - Does not have a diagnosis of primary central nervous system lymphoma

Kymriah is billed using HCPCS code Q2042 – *Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukaphersis and dose preparation procedure, per therapeutic dose*.

## *Cemiplimab-rwlc (Libtayo)*

The IHCP covers cemiplimab-rwlc (Libtayo) with PA. The member must be diagnosed with one of the following:

- Metastatic cutaneous squamous cell carcinoma (CSCC)
- Locally advanced CSCC and not a candidate for curative surgery or curative radiation

The PA limit is six months.

Libtayo is billed using HCPCS code J9119 – *Injection, cemiplimab-rwlc, 1 mg*.

## *Copanlisib (Aliqopa)*

The IHCP covers copanlisib (Aliqopa) therapy with PA. Aliqopa therapy may be considered medically necessary when the member meets ***all*** the following criteria:

- Is 18 years of age or older
- Has a diagnosis of follicular lymphoma
- Has relapsed, refractory or progressive disease
- Has received at least two prior systemic therapies
- Will be using Aliqopa as monotherapy

Aliqopa therapy is not considered medically necessary for members who have experienced disease progression while on or following a PI3K inhibitor (for example, idelalisib, copanlisib).

This agent may be approved in six-month durations or as determined through clinical review. The quantity limit is three 60 mg vials per 28 days. The recommended dose is 60 mg administered as a one-hour intravenous infusion on Days 1, 8 and 15 of a 28-day treatment cycle on an intermittent schedule (three weeks on and one week off), with continued treatment until disease progression or unacceptable toxicity.

Aliqopa is billed using HCPCS code J9057 – *Injection, copanlisib, 1 mg*.

## Durvalumab (Imfinzi)

The IHCP covers durvalumab (Imfinzi) with PA. Imfinzi may be considered medically necessary when the member meets ***all*** the following criteria:

- Is 18 years of age or older
- Has ***one*** of the following:
  - Locally advanced or metastatic urothelial carcinoma with ***one*** of the following:
    - Disease progression during or following platinum-containing chemotherapy
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
  - Non-small cell lung cancer (NSCLC) with ***both*** of the following:
    - Must be unresectable, stage III NSCLC
    - Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy

PA is limited to 12 months. Authorization renewal, which is also limited to 12 months, requires the following criteria be met:

- Locally advanced or metastatic urothelial carcinoma
- No disease progression or unacceptable toxicities

Imfinzi is billed using HCPCS code J9173 – *Imfinzi (durvalumab)*.

## Ibritumomab Tiuxetan (Zevalin)

The IHCP reimburses for radioimmunotherapy with ibritumomab tiuxetan (Zevalin).

Radioimmunotherapy is not a procedure typically performed more than once. Therefore, procedure codes specific to the radioimmunotherapy procedure are limited to one unit per lifetime. The IHCP will reexamine the policy if future research determines that multiple dosing of the radioimmunotherapy regime is appropriate.

Providers should bill the diagnostic supply of Zevalin (A9542), the therapeutic supply of Zevalin (A9543), and the infusion and supply of rituximab (J9312) in the Zevalin regimen.

## Lutetium Lu 177 Dotatate (Lutathera)

The IHCP covers lutetium Lu 177 dotatate (Lutathera) with PA. Lutathera therapy may be considered medically necessary when the member meets ***all*** the following criteria:

- Is 18 years of age or older
- Has a diagnosis of unresectable, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumor (GEP-NET)
- Has somatostatin receptor-based imaging documenting somatostatin receptor-positive GEP-NET
- Has received long-acting somatostatin analog (SSA) therapy (that is, Somatuline Depot or Sandostatin LAR) for a duration of at least 12 weeks
- Has not received a prior course of therapy with Lutathera (that is, maximum of four doses at intervals of at least 8 weeks)

Lutathera therapy is not considered medically necessary for experimental/ investigational use for indications not supported by Centers for Medicare & Medicaid Services (CMS)-recognized compendia or acceptable peer-reviewed literature.

Lutathera is billed using HCPCS code A9513 – *Lutetium Lu 177, dotatate, therapeutic, 1 mCi*.

## *Sipuleucel-T (Provenge)*

The IHCP covers sipuleucel-T (Provenge) with PA. The following medical necessity criteria must be met:

- Diagnosis of metastatic castrate-resistant (hormone-refractory) prostate cancer
- Eastern Cooperative Oncology Group (ECOG) performance status 0–1
- Disease asymptomatic or minimally symptomatic
- Life expectancy greater than six months
- Serum testosterone level less than 50 ng/dL (17 nmol/L)
- No hepatic metastases

Provenge is billed using HCPCS code Q2043 – *Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF including leukapheresis and all other preparatory procedures, per infusion*.

## *Trastuzumab-anns, Biosimilar (Kanjinti)*

The IHCP covers trastuzumab-anns, biosimilar (Kanjinti) with PA. The member must be diagnosed with one of the following:

- HER2 overexpressing breast cancer
- HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma

Kanjinti is billed using HCPCS code Q5117 – *Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg*.