INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Oncology Services

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Revision History

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of Nov. 1, 2018 Published: July 30, 2019	New document	FSSA and DXC
2.0	Policies and procedures as of Feb. 1, 2020 Published: March 13, 2020	Scheduled update	FSSA and DXC
3.0	Policies and procedures as of Feb. 1, 2021 Published: April 20, 2021	Scheduled update	FSSA and Gainwell
4.0	Policies and procedures as of July 1, 2022 Published: Sept. 8, 2022	Scheduled update	FSSA and Gainwell
5.0	Policies and procedures as of Sept. 1, 2024 Published: Jan. 31, 2025	Scheduled update: • Edited text as needed for clarity • Added PathWays to the initial note • Updated the *Ciltacabtagene Autoleucel (Carvykti)* section • Updated the *Idecabtagene Vicleucel (Abecma)* section • Updated the *Lisocabtagene Maraleucel (Breyanzi)* section • Updated the *Cemiplimab-rwlc (Libtayo)* section • Updated the *Durvalumab (Imfinzi)* section • Updated the *Lutetium Lu 177 Dotatate (Lutathera)* section • Updated the *Sipuleucel-T (Provenge)* section • Updated the *Trastuzumab-anns, Biosimilar (Kanjinti)* section	FSSA and Gainwell

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> *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, Hoosier Healthwise or Indiana PathWays for Aging (PathWays) 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 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 Home 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 [IHCP 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, IHCP 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 through the FFS 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
  - 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)

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

Effective for dates of service on or after Oct. 1, 2022, Carvykti is billed using HCPCS code Q2056 – *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*. For prior dates of service, the drug was billed with HCPCS code C9098.

Idecabtagene Vicleucel (Abecma)

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 two* or more prior lines of therapy, including the following:
  - Immunomodulatory agent
  - Proteasome inhibitor
  - Anti-CD38 monoclonal antibody

**Note: For dates of service prior to April 4, 2024, four or more prior lines of therapy were required. Additionally, the maximum dosage for the drug was changed from 460 million cells to 510 million cells.*

Abecma is billed using HCPCS code Q2055 – *Idecabtagene vicleucel, up to 510 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose.*

Lisocabtagene Maraleucel (Breyanzi)

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 one of the following (effective for dates of service on or after March 15, 2024):
  - Relapsed or refractory large B-cell lymphoma, including any of the following, after having received first-line chemoimmunotherapy or 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
  - Relapsed or refractory chronic lymphocytic leukemia or small lymphocytic leukemia after having received at least two prior lines of therapy that includes both of the following:
    - Bruton tyrosine kinase inhibitor
    - B-cell lymphoma 2 inhibitor
  - Relapsed or refractory follicular lymphoma after having received at least two prior lines of systemic therapy
- 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*.

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
    - 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. Effective for dates of service on or after Dec. 9, 2022, Libtayo may be considered medically necessary for members with one of the following diagnoses:

- Basal cell carcinoma (BCC) that meets both of the following:
  - Metastatic or locally advanced
  - Previously treated with a hedgehog pathway inhibitor, or a hedgehog pathway inhibitor is not appropriate
- Non-small cell lung cancer (NSCLC) that meets all the following:
  - Metastatic or locally advanced
  - Ineligible for surgical resection or definitive chemoradiation
  - One of the following:
    - Single agent
      - High PD-L1
      - No EGFT, ALK or ROS1 aberrations
    - Combination therapy
      - No EGFT, ALK or ROS1 aberrations
- Cutaneous squamous cell carcinoma (CSCC) of skin that meets both of the following:
  - Metastatic or locally advanced
  - In patients who are not candidates 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
- Effective for dates of service on or after Dec. 9, 2022, has a diagnosis of ***one*** of the following:
  - Extensive stage small cell lung cancer (ES-SCLC)
    - Treatment must be in combination with etoposide and platinum-based therapy (CARBOplatin or CISplatin)
  - 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
  - Biliary tract cancer:
    - Must be unresectable and metastatic
    - Treatment must be in combination with gemcitabine and cisplatin therapy
  - Urothelial carcinoma:
    - Must be locally advanced or metastatic

PA is limited to 12 months. Authorization renewal, which is also limited to 12 months, requires the patient has had 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). Zevalin is a CD20-directed radiotherapeutic antibody administered as part of the Zevalin therapeutic regimen indicated for treatment of the following patients:

- Adults with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL)
- Adults with previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy

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.

Radioimmunotherapy is not a procedure typically performed more than once. Therefore, procedure codes specific to the radioimmunotherapy procedure (A9542 and A9543) 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.

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 somatostatin receptor-positive for locally unresectable disease or distant metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (effective for dates of service on or after Dec. 9, 2022)
- 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 eight weeks)

Lutathera therapy is not considered medically necessary for experimental or 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. Effective for dates of service on or after Dec. 9, 2022, Provenge may be considered medically necessary when the member meets ***all*** the following criteria:

- Is 18 years of age or older
- Has a diagnosis of metastatic castrate-resistant (hormone-refractory) prostate cancer
- Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0–1
- Has asymptomatic or minimally symptomatic disease
- Has a serum testosterone level that is less than 50 ng/dL

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. Kanjinti may be considered medically necessary when the member meets ***all*** the following criteria:

- Is 18 years of age or older (effective for dates of service on or after Dec. 9, 2022)
- Has a diagnosis of 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*.