Oncology Services
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<tr>
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<td>Policies and procedures as of November 1, 2018&lt;br&gt;Published: July 30, 2019</td>
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| 2.0     | Policies and procedures as of February 1, 2020<br>Published: March 13, 2020 | Scheduled update:  
- Edited text as needed for clarity  
- Updated the initial note box with standard wording  
- Removed the Prior Authorization for Oncology Services section  
- Added a note about prior authorization to the Chemotherapy and Radiation as Outpatient Hospital Services section  
- Updated the code for rituximab in the Radioimmunotherapy section  
- Added the Cemiplimab-rwlc (Libtayo) section  
- Updated the procedure code in the Copanlisib (Aliqopa) section  
- Updated the procedure code in the Durvalumab (Imfinzi) section  
- Updated the procedure code in the Lutetium Lu 177 Dotatate (Lutathera) section  
- Added the Moxetumomab pasudotox-tdfs (Lumoxiti) section  
- Added the Sipuleucel-T (Provenge) section  
- Added the Tisagenlecleucel (Kymriah) section  
- Added the Trastuzumab-anns, Biosimilar (Kanjinti) section | FSSA and DXC |
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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 (including coverage and prior authorization requirements), see the Surgical Services module.

Chemotherapy and Radiation as Outpatient Hospital Services

In accordance with Indiana Administrative Code 405 IAC 5-28-10, outpatient administration of chemotherapy and costs related to this therapy (including catheterization, physician visits, cost of drugs and solutions, pump regulators, and servicing) are covered and do not require prior authorization.

All outpatient hospital chemotherapy and radiation treatment services are billed on the institutional claim (UB-04 claim form, 837I electronic transaction, or IHCP Provider Healthcare Portal [Portal] institutional claim). 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 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, 837P electronic transaction, or Portal professional claim).

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

Radioimmunotherapy is not a procedure typically performed more than once. Therefore, 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 ibritumomab tiuxetan (Zevalin) (A9542), the therapeutic supply of Zevalin (A9543), and the infusion and supply of rituximab (J9312) in the Zevalin regimen.

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 prior authorization requests for gene therapy must include a letter of medical necessity and supportive patient/clinical chart documents demonstrating member diagnosis requirements.

### Cemiplimab-rwlc (Libtayo)

For dates of service on or after April 1, 2019, the IHCP covers cemiplimab-rwlc (Libtayo) with prior authorization. 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 prior authorization limit is 6 months.

For dates of service on or after October 1, 2019, this service is billed using HCPCS code J9119 – *Injection, cemiplimab-rwlc, 1 mg*. For dates of service from April 1, 2019, through September 30, 2019, HCPCS code C9044 is used to bill this service.

### Copanlisib (Aliqopa)

The IHCP covers copanlisib (Aliqopa) therapy with prior authorization. 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 6-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 1-hour intravenous infusion on Days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (3 weeks on and 1 week off), with continued treatment until disease progression or unacceptable toxicity.

For dates of service on or after January 1, 2019, this service is billed using HCPCS code J9057 – *Injection, copanlisib, 1 mg*. 
**Durvalumab (Imfinzi)**

The IHCP covers durvalumab (Imfinzi) with prior authorization. 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

Prior authorization 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

For dates of service on or after January 1, 2019, this service is billed using HCPCS code J9173 – *Imfinzi (durvalumab)*.

**Lutetium Lu 177 Dotate (Lutathera)**

The IHCP covers lutetium Lu 177 dotate (Lutathera) with prior authorization. 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.

For dates of service on or after January 1, 2019, this service is billed using HCPCS code A9513 – *Lutetium Lu 177, dotate, therapeutic, 1 mCi*.
Moxetumomab pasudotox-tdfk (Lumoxiti)

For dates of service on or after April 1, 2019, the IHCP covers moxetumomab pasudotox-tdfk (Lumoxiti).

For dates of service on or after October 1, 2019, this service is billed using HCPCS code J9313 – Injection, moxetumomab pasudotox-tdfk, 0.01 mg, and prior authorization is not required.

For dates of service from April 1, 2019, through September 30, 2019, this service is billed using HCPCS code C9045, and prior authorization is required. For prior authorization of C9045, the member must meet both the following criteria:

- Diagnosis of relapsed or refractory hairy cell leukemia (HCL)
- Failed at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)

Sipuleucel-T (Provenge)

The IHCP covers sipuleucel-T (Provenge) with prior authorization. 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 6 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.

Tisagenlecleucel (Kymriah)

The IHCP covers tisagenlecleucel (Kymriah) with prior authorization. Kymriah may be considered medically necessary when all the following criteria are met:

- Member has not received prior tisagenlecleucel treatment.
- Member will be administered tisagenlecleucel treatment:
  - At a Kymriah Risk Evaluation and Mitigation Strategy (REMS) Program-certified facility
  - By healthcare providers who have successfully completed the Kymriah REMS Program Knowledge Assessment
- 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 and is not a primary central nervous system lymphoma

For dates of service on or after January 1, 2019, this service is billed using HCPCS code Q2042 – Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedure, per therapeutic dose. For dates of service from January 1, 2018, through December 31, 2018, this service is billed using HCPCS code Q2040, which did not require prior authorization.
**Trastuzumab-anns, Biosimilar (Kanjinti)**

For dates of service on or after October 1, 2019, the IHCP covers trastuzumab-anns, biosimilar (Kanjinti) with prior authorization. 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.*