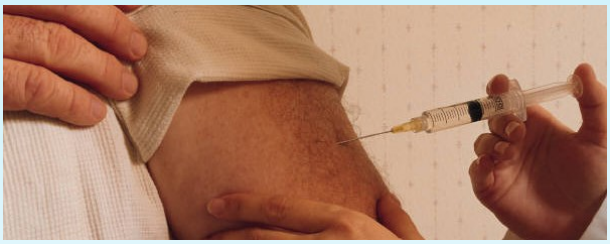
IHCP *bulletin*

INDIANA HEALTH COVERAGE PROGRAMS BT202296 NOVEMBER 8, 2022

IHCP updates physician-administered drug PA criteria and diagnosis restrictions

The Indiana Health Coverage Programs (IHCP) announces updates to prior authorization (PA) criteria and diagnosis restrictions for several physician-administered drugs. The updates are effective for claims with dates of service (DOS) on or after Dec. 9, 2022, as shown in the following tables:

- Table 1 – Physician-administered drugs with updated PA criteria
- Table 2 – Physician-administered drugs that now require PA
- Table 3 – Physician-administered drugs that no longer have diagnosis restrictions



PA criteria updates are based upon a comprehensive review of the following:

- PA criteria currently posted in the following provider reference modules:
  - *Injections, Vaccines and Other Physician-Administered Drugs*
  - *Oncology Services*
  - *Vision Services*
- Established fee-for-service (FFS) pharmacy benefit criteria
- Current Food and Drug Administration (FDA) labeling and approved compendia recommendations

Table 1 – Physician-administered drugs with updated PA criteria for claims with DOS on or after Dec. 9, 2022

Procedure code	Physician-administered drug	Updated PA criteria
A9513	Lutetium Lu 177 Dotatate (Lutathera)	IHCP coverage of lutetium Lu 177 dotatate (Lutathera) requires prior authorization. This agent 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 metastases gastroenteropancreatic neuroendocrine tumors (GEP-NETs). • 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.

Table 1 – Physician-administered drugs with updated PA criteria for claims with DOS on or after Dec. 9, 2022 (Continued)

Procedure code	Physician-administered drug	Updated PA criteria
J0791	Crizanlizumab-tmca (Adakveo)	IHCP coverage of crizanlizumab-tmca (Adakveo) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member meets the following: – Is 16 years or older. – Has a diagnosis of a sickle cell disease, including but not limited to homozygous hemoglobin S, sickle hemoglobin C disease, sickle beta 0 thalassemia and sickle beta + thalassemia. – Is currently receiving hydroxyurea therapy; or member has a history of intolerance or contraindication to hydroxyurea therapy. – Has experienced one of the following: ♦ At least two sickle cell-related vaso-occlusive crises within the previous 12 months while concurrently receiving hydroxyurea therapy. ♦ At least two sickle cell-related vaso-occlusive crises within the previous 12 months and has an intolerance or contraindication to hydroxyurea therapy. • Adakveo is prescribed by, or in consultation with, a hematologist or other prescriber specialized in the treatment of sickle cell disease. • Dose is 5 mg/kg IV at week 0, week 2 and every four weeks thereafter; patient weight must be provided to confirm dose.
J1426	Casimersen (Amondys 45)	IHCP coverage of casimersen (Amondys 45) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member must have a documented diagnosis of Duchenne muscular dystrophy (DMD), with confirmed mutation of the DMD gene that is amenable to exon 45 skipping. • Dosage is 30 mg/kg once weekly; patient weight must be provided to confirm dose. • Prescriber must provide documentation of current clinical status (for example, Brooke Score, six-minute walk test, and so on) to compare upon reevaluations of therapy. • For reauthorization, documentation must demonstrate improvement (including stabilization) in current clinical status. • Amondys 45 is not used concomitantly with other exon-skipping therapies for DMD.
J1428	Eteplirsen (Exondys 51)	IHCP coverage of eteplirsen (Exondys 51) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member must have a documented diagnosis of DMD, with confirmed mutation of the DMD gene that is amenable to exon 51 skipping. • Dosage is 30 mg/kg once weekly; patient weight must be provided to confirm dose. • Prescriber must provide documentation of current clinical status (for example, Brooke Score, six-minute walk test and so on) to compare upon reevaluations of therapy. • For reauthorization, documentation must demonstrate improvement (including stabilization) in current clinical status.

Table 1 – Physician-administered drugs with updated PA criteria for claims with DOS on or after Dec. 9, 2022 (Continued)

Procedure code	Physician-administered drug	Updated PA criteria
J1429	Golodirsen (Vyondys 53)	IHCP coverage of golodirsen (Vyondys 53) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member must have a documented diagnosis of DMD with confirmed mutation of the DMD gene that is amenable to exon 53 skipping. • Dosage is 30 mg/kg once weekly; patient weight must be provided to confirm dose. • Prescriber has validated that member is not currently experiencing renal toxicity. • Prescriber must provide documentation of current clinical status (for example, Brooke Score, six-minute walk test and so on) to compare upon reevaluations of therapy. • For reauthorization, documentation must demonstrate improvement (including stabilization) in current clinical status.
J2326	Nusinersen (Spinraza)	IHCP coverage of nusinersen (Spinraza) requires prior authorization. This agent may be considered medically necessary for the treatment of spinal muscular atrophy (SMA) in members who meet both criteria A and B: • Criteria A – Documentation of confirmatory diagnosis by one of the following: – SMA diagnostic test results confirming zero copies of the SMN1 gene – Molecular genetic testing of 5q SMA for any of the following: ♦ Homozygous gene deletion ♦ Homozygous conversion mutation ♦ Compound heterozygote • Criteria B – Documentation of one of the following: – Genetic testing confirming no more than three copies of the SMN2 gene – SMA-associated symptoms before 6 months of age Continuation of treatment with nusinersen beyond six months after the initiation of therapy, and every four months thereafter, is considered medically necessary for the treatment of SMA when members meet both of the following criteria: • Initial therapy was determined to meet the preceding criteria (A and B). • Submitted documentation shows clinically significant improvement in SMA-associated symptoms (for example, progression, stabilization or decrease in the rate of decline in motor function) compared to the predicted natural history trajectory of the disease. Nusinersen is not considered medically necessary when used under the following treatment scenarios: • Post onasemnogene abeparvovec-xioi treatment • Concurrently with risdiplam

Table 1 – Physician-administered drugs with updated PA criteria for claims with DOS on or after Dec. 9, 2022 (Continued)

Procedure code	Physician-administered drug	Updated PA criteria
J2507	Pegloticase (Krystexxa)	IHCP coverage of pegloticase (Krystexxa) requires prior authorization. This agent may be considered medically necessary for the treatment of members with gout when criteria A, B and C are met: • Criteria A – Symptomatic gout with one or more of the following: – Three gouty flares or more in previous 18 months – Presence of one or more tophi – Chronic gouty arthritis • Criteria B – Serum uric acid level: – Serum uric acid level greater than 8 mg/dL at initiation – Serum uric acid levels do not exceed 6 mg/dL for continuation of therapy • Criteria C – Treatment with oral xanthine oxidase inhibitors with one of the following (*Note: Xanthine oxidase inhibitors should be discontinued prior to initiating pegloticase.*): – A 90-day course of each of two xanthine oxidase inhibitor alternatives (such as allopurinol and febuxostat) is ineffective in normalizing serum uric acid levels to less than 6 mg/dL. – Intolerance to two xanthine oxidase inhibitor alternatives (such as allopurinol and febuxostat) occurs. – Use of two xanthine oxidase inhibitors alternatives (such as allopurinol and febuxostat) is contraindicated. Coverage is limited to one 8 mg infusion every two weeks, not to exceed 26 infusions in one year. Pegloticase is considered investigational when used for all other conditions, including but not limited to hyperuricemia not associated with gout and asymptomatic hyperuricemia.
J3032	Eptinezumab-jjmr (Vyepti)	IHCP coverage of eptinezumab-jjmr (Vyepti) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member meets the following: – Is 18 years of age or older. – Has a diagnosis of migraine with or without aura requiring prophylaxis. • All the following have either been tried and failed, or there is documented intolerance or contraindication for their use: – Divalproex, valproate, topiramate, metoprolol, propranolol, timolol and tricyclic antidepressant – Aimovig – Emgality • Quantity does not exceed 3 mL/90 days.
J3111	Romosozumab-aqqg (Evenity)	IHCP coverage of romosozumab-aqqg (Evenity) requires prior authorization. This agent may be considered medically necessary when the member meets all the following criteria: • Is 18 years of age or older. • Is postmenopausal woman with osteoporosis. • Has high risk for bone fracture. • Has history of failure, contraindication or intolerance to oral or intravenous bisphosphonate therapy. • Has no myocardial infraction or stroke in the previous year. • Has no uncorrected hypocalcemia. • Has no osteonecrosis of the jaw. Coverage is limited to a one-year duration of therapy over the course of the member's lifetime.

Table 1 – Physician-administered drugs with updated PA criteria for claims with DOS on or after Dec. 9, 2022 (Continued)

Procedure code	Physician-administered drug	Updated PA criteria
J3398	Voretigene Neparvovec-rzyl (Luxturna)	IHCP coverage of voretigene neparvovec-rzyl (Luxturna) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member meets the following: – Is greater than 12 months of age. – Has a confirmed diagnosis of biallelic RPE65 mutation-associated retinal dystrophy (for example, Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP] or early-onset severe retinal dystrophy [EOSRD]). ♦ Genetic testing documents biallelic mutations of the RPE65 gene. – Has sufficient viable retinal cells, as determined by treating physician. – Has not previously received RPE65 gene therapy in the intended eye. • Luxturna treatment is prescribed and will be administered by an ophthalmologist or retinal surgeon with experience providing subretinal injections. • Dose does not exceed 0.3 mL per eye (two vials total).
J7311	Fluocinolone Acetonide Intravitreal Implant (Retisert)	IHCP coverage of fluocinolone acetonide intravitreal implant (Retisert) requires prior authorization. This agent may be considered medically necessary when the member meets all the following criteria: • Is 12 years of age or older. • Has a diagnosis of chronic, noninfectious uveitis affecting the posterior segment of the eye. • Has previously tried and failed conventional treatments (including corticosteroid therapy, methotrexate, mycophenolate, azathioprine, cyclosporine, tacrolimus, cyclophosphamide, or adalimumab), or medical justification is provided for use over these therapies.
J9119	Cemiplimab-rwlc (Libtayo)	IHCP coverage of cemiplimab-rwlc (Libtayo) requires prior authorization. This agent may be considered medically necessary for members with one of the following diagnoses: • Basal cell carcinoma (BCC), metastatic or locally advanced, previously treated with a hedgehog pathway inhibitor or when a hedgehog pathway inhibitor is not appropriate • Non-small cell lung cancer (NSCLC), metastatic or locally advanced disease ineligible for surgical resection or definitive chemoradiation, high PD-L1, first-line, with no EGFT, ALK, or ROS1 aberrations • Cutaneous Squamous cell carcinoma of skin (CSCC), metastatic or locally advanced disease, in patients who are not candidates for curative surgery or curative radiation Prior authorization is limited to six months.

Table 1 – Physician-administered drugs with updated PA criteria for claims with DOS on or after Dec. 9, 2022 (Continued)

Procedure code	Physician-administered drug	Updated PA criteria
J9173	Durvalumab (Imfinzi)	IHCP coverage of durvalumab (Imfinzi) requires prior authorization. This agent may be considered medically necessary when the member meets all the following criteria: • Is 18 years of age or older. • Has a diagnosis of one of the following: – Extensive stage small cell lung cancer (ES-SCLC) with the following: ♦ 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. – Unresectable and metastatic biliary tract cancer ♦ Treatment must be in combination with gemcitabine and cisplatin therapy. – Locally advanced or metastatic urothelial carcinoma Prior authorization is limited to 12 months. Authorization renewal, which is also limited to 12 months, requires the following criteria be met: • No disease progression or unacceptable toxicities
Q2043	Sipuleucel-T (Provenge)	IHCP coverage of sipuleucel-T (Provenge) requires prior authorization. This agent 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 (nmol/L).
Q5117	Trastuzumab-anns, Biosimilar (Kanjinti)	IHCP coverage of trastuzumab-anns, biosimilar (Kanjinti) requires prior authorization. This agent may be considered medically necessary when the member meets all the following criteria: • Is 18 years of age or older. • Has a diagnosis of one of the following: – HER2 overexpressing breast cancer – HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma
Q9991, Q9992	Buprenorphine Extended-Release (Sublocade)	IHCP coverage of buprenorphine extended-release (Sublocade) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member is 18 years of age or older. • One of the following has occurred: – Member has tried and failed each of the preferred agents listed on the pharmacy benefit Preferred Drug List (PDL) (submit chart notes that document failures). – Prescriber has provided documentation of member-specific medically justifiable reason(s) that all the pharmacy benefit preferred agents are not suitable for use for this member. • Initial dose is less than or equal to 300 mg/month. • Subsequent doses are less than or equal to 100 mg/month.

Table 2 – Physician-administered drugs that now require PA for claims with DOS on or after Dec. 9, 2022

Procedure code	Physician-administered drug	Updated PA criteria
J7314	Fluocinolone Acetonide Intravitreal Implant (Yutiq)	IHCP coverage of fluocinolone acetonide intravitreal implant (Yutiq) requires prior authorization. This agent may be considered medically necessary when the member meets all the following criteria: • Is 18 years of age or older. • Has a diagnosis of chronic, noninfectious uveitis affecting the posterior segment of the eye. • Has previously tried and failed conventional treatments (including corticosteroid therapy, methotrexate, mycophenolate, azathioprine, cyclosporine, tacrolimus, cyclophosphamide, or adalimumab), or medical justification is provided for use over these therapies.
J9225	Histrelin Implant (Vantas)	IHCP coverage of histrelin implant (Vantas) requires prior authorization. This agent may be considered medically necessary when all the following criteria are met: • Member meets the following: – Is 18 years of age or older. – Has a medical need for the implant (such as mobility or compliance issues, or inability to receive daily injections). – Has not had a bilateral orchiectomy. • Submitted documentation shows a diagnosis of cancer of the prostate. • For reauthorization, a demonstrated response to luteinizing hormone-releasing hormone (LHRH) agonists has been confirmed by periodic measurement of testosterone and prostate-specific antigen (PSA) levels. Vantas is limited to one unit per member per year.

Table 3 – Physician-administered drugs that no longer have diagnosis restrictions for claims with DOS on or after Dec. 9, 2022

Procedure code	Physician-administered drug
J1951	Leuprolide Acetate (Fensolvi)
J9226	Histrelin Implant (Supprelin LA)

This information will be reflected in the next regular update to the Outpatient Fee Schedule and the Professional Fee Schedule, accessible from the *IHCP Fee Schedules* page at in.gov/medicaid/providers.

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