

PRIOR AUTHORIZATION CRITERIA

CATEGORY

SELF INJECTABLES

BRAND NAME (generic)

(cyanocobalamin b12 injection)

DELESTROGEN
(estradiol valerate in oil)

DEPO-ESTRADIOL
(estradiol cypionate in oil)

DEPO-PROVERA
(medroxyprogesterone acetate suspension 400 mg/ml)

(heparin injection)

SOLU-CORTEF
(hydrocortisone sodium succinate)

Status: Client Requested Criteria
Type: Initial Prior Authorization

Ref # C6947-A

POLICY

FDA-APPROVED INDICATIONS

Cyanocobalamin (vitamin B12) injection

Cyanocobalamin (vitamin B12) for injection is indicated for:

- treatment of pernicious anemia or vitamin B12 deficiency due to dietary deficiencies, gastrointestinal malabsorption, folic acid deficiency, parasitic infestation, inadequate secretion of intrinsic factor, or inadequate utilization of B12 (e.g. during neoplastic treatment)
- prevention of vitamin B12 deficiency in patients with increased B12 requirements (e.g. due to pregnancy, thyrotoxicosis, hemorrhage, malignancy, liver or kidney disease)

Delestrogen

Delestrogen for injection is indicated for:

- moderate to severe vasomotor symptoms associated with menopause
- moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause
- hypoestrogenism due to hypogonadism, castration, or primary ovarian failure
- advanced androgen-dependent carcinoma of the prostate (for palliation only)

Compendial Use:

- Estradiol (usually in combination with antiandrogen therapy in patients who have not undergone gender-affirming genital surgery) is effective and recommended for elevating serum estradiol and

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suppressing serum testosterone levels into the normal female range to achieve desired physical changes

Depo-Estradiol

Depo-estradiol for injection is indicated for:

- moderate to severe vasomotor symptoms associated with menopause
- hypoestrogenism due to hypogonadism

Compendial Use:

- Estradiol (usually in combination with antiandrogen therapy in patients who have not undergone gender-affirming genital surgery) is effective and recommended for elevating serum estradiol and suppressing serum testosterone levels into the normal female range to achieve desired physical changes

Limitations of Use:

- When prescribing Delestrogen solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered.

Depo-Provera 400mg

Depo-Provera 400mg for injection is indicated as adjunctive therapy and palliative treatment of inoperable, recurrent, and metastatic endometrial or renal carcinoma.

Limitations of Use:

- Depo-Provera 400mg for injection should be avoided in patients with active thrombophlebitis, or current or past history of thromboembolic disorders, or cerebral vascular disease.

Heparin

Heparin sodium for injection is indicated for:

- prophylaxis and/or treatment of thromboembolic disorders (e.g. venous thromboembolism, pulmonary embolism) and thromboembolic complications associated with atrial fibrillation or other disease states
- prevention of clotting in arterial and cardiac surgery
- as an anticoagulant for blood transfusions, extracorporeal circulation, and dialysis procedures

Solu-Cortef

Solu-Cortef for injection is indicated for:

- *Allergic states:* control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, serum sickness, and transfusion reactions
- *Dermatologic diseases:* bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome).
- *Endocrine disorders:* Primary or secondary adrenocortical insufficiency, congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis.
- *Gastrointestinal diseases:* to tide the patient over a critical period of the disease in regional enteritis (systemic therapy) and ulcerative colitis
- *Hematologic disorders:* Acquired (autoimmune) hemolytic anemia, congenital (erythroid) hypoplastic anemia (Diamond Blackfan anemia), idiopathic thrombocytopenic purpura in adults (intravenous administration only; intramuscular administration is contraindicated), pure red cell aplasia, select cases of secondary thrombocytopenia

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- *Miscellaneous*: Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy
- *Neoplastic diseases*: For the palliative management of leukemias and lymphomas
- *Nervous System*: Cerebral edema associated with primary or metastatic brain tumor, or craniotomy.
- *Ophthalmic diseases*: Sympathetic ophthalmia, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids
- *Renal diseases*: To induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome, or that due to lupus erythematosus
- *Respiratory diseases*: Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis
- *Rheumatic disorders*: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, temporal arteritis, polymyositis, and systemic lupus erythematosus.

Limitations of Use:

- In primary or secondary adrenocortical insufficiency, hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance
- Solu-Cortef for injection is contraindicated in systemic fungal infections.
- Intramuscular corticosteroid preparations, including Solu-Cortef, are contraindicated for idiopathic thrombocytopenic purpura.
- Solu-Cortef for injection should not be used for intrathecal administration. Reports of severe medical events have been associated with this route of administration.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is not being administered in a physician's office

AND

- The requested drug is being administered by the patient, or care provider, outside of the physician's office

AND

- The patient and/or caregiver has been trained to self-administer the requested medication

AND

- The training to self-administer the requested medication has been documented in the patient's chart

Duration of Approval (DOA):

- C6947-A: DOA: 60 months

REFERENCES

1. Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.
2. Cyanocobalamin injection [prescribing information]. E. Windsor, NJ: AuroMedics Pharma LLC; May 2020.

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3. Delestrogen (estradiol valerate) [prescribing information]. Chestnut Ridge, NY: Par Pharmaceutical; February 2024.
4. Depo-Estradiol (estradiol cypionate) [prescribing information]. New York, NY: Pharmacia & Upjohn Company LLC; June 2019.
5. Heparin sodium injection (single- and multi-dose vials) [prescribing information]. Lake Zurich, IL: Fesenius Kabi; June 2021.
6. Depo-Provera (medroxyprogesterone acetate) [prescribing information]. New York, NY: Pfizer; April 2017.
7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. *Endocr Pract.* 2017;23(12):1437.
8. Heparin sodium injection (single- and multi-dose vials) [prescribing information]. Lake Zurich, IL: Fesenius Kabi; June 2021.
9. Heparin sodium injection (single- and multi-dose vials) [prescribing information]. Schaumburg, IL: Sagent Pharmaceuticals; May 2022.
10. Solu-Cortef (hydrocortisone sodium) [prescribing information]. New York, NY: Pharmacia & Upjohn Co; July 2024.