

Policy: MP144

Section: Medical Benefit Policy

Subject: Injectable Vitamin B12 Therapy

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Injectable Vitamin B₁₂ Therapy

II. Purpose/Objective:

To provide a policy of coverage regarding Injectable Vitamin B₁₂ Therapy

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Vitamin B₁₂, also known as cobalamin plays an essential role in DNA synthesis, cell maturation and neurologic function. Deficiency results in a wide spectrum of anemias and neuropsychiatric disorders.

INDICATIONS:

Injectable vitamin B₁₂ therapy is considered medically necessary with any of the following conditions:

1. Anemia
 - Pernicious anemia
 - Macrocytic anemia
 - Fish tapeworm anemia
 - Megaloblastic anemia
2. Gastrointestinal disorders
 - Malabsorption syndromes such as but not limited to sprue and idiopathic steatorrhea
 - Surgical or mechanical disorders such as resection of the small intestine, intestinal stricture, intestinal anastomosis, blind loop syndrome, and total or partial gastrectomy
 - Conditions associated with decreased production of intrinsic factor
3. Neuropathies
 - Posteriolateral sclerosis
 - Neuropathy associated with pernicious anemia
 - Acute phase or exacerbation of neuropathy secondary to malnutrition or alcoholism
4. Methylmalonic aciduria
5. Homocystinuria
6. Retrobulbar neuritis associated with heavy smoking (tobacco amblyopia)
7. Dementia secondary to vitamin B₁₂ deficiency
8. As part of a pre-medication regimen prior to and during treatment with certain drugs/biologicals, with potential significant adverse effects, such as provided with Pemetrexed for injection (Alimta) or pralatrexate (Folotyn).

LIMITATIONS:

Vitamins including oral B₁₂ supplements that can be purchased without a prescription are **NOT COVERED** unless listed as specifically covered under an OTC drug benefit in the Medicaid business segment.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Injectable Vitamin B₁₂ Therapy

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- J3420 Injection, vitamin B₁₂ Cyanocobalamin, up to 1000 mcg
- J9307 Injection, pralatrexate, per 1 mg
- 82607 Cyanocobalamin

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Dharmarajan TS, Norkus EP, " Approaches to vitamin B₁₂ deficiency" Postgraduate Medicine. July 2001; 110(1).

Oh RC, Brown DL, "Vitamin B₁₂ deficiency", American Family Physician. 2003;67:979-986, 993-994.

Skroubis G, Sakellaropoulos G, et. al., "Comparison of nutritional deficiencies after Roux-en-Y gastric bypass and after biliopancreatic diversion with Roux-en-Y gastric bypass", Obesity Surgery. 2002 Aug; 12(4):551-558.

Misra UK, Kalita J, Das A, " Vitamin B12 deficiency neurological syndromes: a clinical, MRI and electrodiagnostic study", Electromyography & Clinical Neurophysiology. 2003 Jan-Feb; 43(1):57-64.

Schriner SL. Diagnosis and treatment of vitamin B12 and folate deficiency. UptoDate Sep 21, 2016., June 2021

Schriner SL. Etiology and clinical manifestations of vitamin B12 and folate deficiency. UptoDate Jul 15, 2016

Kwok T, Lee J, Ma RC, et al. A randomized placebo controlled trial of vitamin B12 supplementation to prevent cognitive decline in older diabetic people with borderline low serum vitamin B12. Clin Nutr. 2017;36(6):1509-1515

Alimta Prescribing Information

Folotyn™ Prescribing Information.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/04

Revised: 8/07 (updated indication as per CMS); 5/22 (update indications)

Reviewed: 8/05; 8/06; 8/08; 6/09; 6/10, 6/11, 6/12, 6/13, 6/14, 6/15, 12/16, 5/17, 5/18, 5/19, 5/20, 5/21, 5/23, 5/24

CMS UM Oversight Committee Approval: 12/23, 7/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.