

Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

☒ **Commercial (Small & Large Group)** ☒ **ASO** ☒ **Exchange/ACA**
☐ **Medicare Advantage (MAPD)**

Levothyroxine Intravenous**MB2121**

Covered Service: Yes

**Prior Authorization
Required:** Yes

**Additional
Information:** Prescribed by (or in consultation with) Medical physician with
prior authorization through The Plan Pharmacy Services.

Medicare Policy: Prior authorization is not required for Medicare Cost products
(Dean Care Gold) and Medicare Supplement (Select) when this
drug is provided by participating providers. Prior authorization is
required if a member has Medicare primary and the plan
secondary coverage. This policy is not applicable to our
Medicare Replacement products.

**Wisconsin
Medicaid Policy** Coverage of prescription drug benefits is administered by the
Wisconsin Medicaid program. Coverage of medical drug benefits
is administered by the Wisconsin Medicaid fee-for-service
program. Medical drugs not paid on a fee-for-service basis by the
Wisconsin Medicaid program are covered by the plan with no PA
required.

1.0 FDA Indication: Intravenous Levothyroxine therapy will not be covered in an
outpatient setting for any substitution for oral therapy for an off-labeled indications such
as replacement for an oral therapy,

2.0 True clinical benefit has not been established for off labeled uses of Intravenous
Levothyroxine based on the following:

2.1 The substitution of levothyroxine Sodium Injection to oral levothyroxine sodium
has not established a relative bioavailability, therefore creates a risk of an
inaccurate dose conversion.

2.2 The need for larger, controlled trials are needed to confirm dosage conversion.

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2.3 Due to inability to have stable dosing conversion there is limited safety profile with the use of IV levothyroxine is being substituted for oral therapy.

Comment(s):

1.0 Documentation is expected to be maintained in the member's medical record and available to the plan. Every page of the record is expected to be legible and include both the appropriate member identification information (e.g., complete name dates of service(s)), and information identifying the physician or non-physician practitioner responsible for and providing the care of the member. The member's medical record must contain documentation that fully supports the medical necessity for services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

1.1 The medical record must include the following information:

1.1.1 A physician's order

1.1.2 The name of the drug or biological administered

1.1.3 The route of administration

1.1.4 The dosage (e.g., mgs, mcgs, cc's or IU's)

2.0 When a portion of the drug or biological is discarded, the medical record must clearly document the amount administered and the amount wasted or discarded

3.0 *.Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

3.1 NDC and HCPCS codes

Medication Name		How Supplied	National Drug Code (NDC)	HCPCS code
Brand	Generic			
Levothyroxine Sodium for injection	Levothyroxine Sodium for injection	100 mcg/vial	42023-0201-01 63323-0649-07 63323-0649-16 63323-0649-21 63323-0649-94	J3490

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			70860-0451-10	
		100 MCG/5ML	63323-0885-10 63323-0885-12 63323-0885-14	
		200 MCG	42023-0202-01 63323-0647-10 63323-0647-21 70860-0452-10	
		200 MCG/5ML	63323-0890-10	
		500 MCG	42023-0203-01 63323-0648-10 63323-0648-21 70860-0453-10	
		500 MCG/5ML	63323-0895-10	

4.0 NOTE: The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.

Committee/Source

Date(s)

Document Medical Policy Committee/Health Services

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References:

1. Levothyroxine [prescribing information]. Schaumburg, IL: APP Pharmaceuticals; June 2011.
2. Generall,J, Cada, D. Off-Label Drug Uses - Thyroxine: Once-Weekly Administration for Hypothyroidism, Sept 2009 Hospital Pharmacy 44(9):748-750; DOI:10.1310/hpj4409-748.