MULTIVIT34/FOLIC ACID/NADH/COQ10

Generic	Brand	HICL	GCN	Exception/Other
MULTIVIT34/FOLIC ACID/NADH/COQ10	MEBOLIC, ZYVIT, XYZBAC	43222		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have both the diagnoses of folate deficiency and vitamin B12 deficiency and meet **ALL** of the following criteria?
   - The advanced nature of the patient's vitamin B12 and folate deficiencies is supported by physician attestation that at least **ONE** of the following clinical features consistent with severe vitamin deficiency is present:
     - symptomatic anemia
     - gastrointestinal symptoms (e.g., glossitis, mouth ulcers)
     - psychiatric or neurological symptoms (e.g., cognitive impairment, dementia, depression, symmetric paresthesia, numbness, or gait problems)
   - The patient has a serum folate < 2.0 ng/mL (below 4.5 nmol/L or below laboratory specific lower limit of normal is acceptable)
   - The patient has a serum vitamin B12 < 200 pg/mL (below 148 pmol/L or below laboratory specific lower limit of normal is acceptable)
   - The patient has had a trial for at least four months of or has a contraindication to treatment doses of folic acid (e.g., 1 to 5 mg orally daily)
   - The patient has had a trial for at least 4 months of or has a contraindication to treatment doses of vitamin B12 (e.g., cyanocobalamin 1000-2000 mcg orally daily, 100 mcg intramuscularly daily to monthly)
   - The patient has had a trial of or has a contraindication to a multivitamin (OTC)

   If yes, **approve for 4 months by GPID (40914) with a quantity limit of #30 tablets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MULTIVIT34/FOLIC ACID/NADH/COQ10

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **MULTIVIT34/FOLIC ACID/NADH/COQ10 (Mebolic, Zyvit, Xyzbac)** requires the diagnosis of folate deficiency and vitamin B12 deficiency. In addition, the following criteria must be met:

- The advanced nature of the patient's vitamin B12 and folate deficiencies is supported by physician attestation that at least **ONE** of the following clinical features consistent with severe vitamin deficiency is present:
  - symptomatic anemia
  - gastrointestinal symptoms (e.g., glossitis, mouth ulcers)
  - psychiatric or neurological symptoms (e.g., cognitive impairment, dementia, depression, symmetric paresthesia, numbness, or gait problems)
- The patient has a serum folate < 2.0 ng/mL (below 4.5 nmol/L or below laboratory specific lower limit of normal is acceptable)
- The patient has a serum vitamin B12 < 200 pg/mL (below 148 pmol/L or below laboratory specific lower limit of normal is acceptable)
- The patient has had a trial for at least four months of or has a contraindication to treatment doses of folic acid (e.g., 1 to 5 mg orally daily)
- The patient has had a trial for at least 4 months of or has a contraindication to treatment doses of vitamin B12 (e.g., cyanocobalamin 1000-2000 mcg orally daily, 100 mcg intramuscularly daily to monthly)
- The patient has tried or has a contraindication to a multivitamin (OTC)

RENEWAL CRITERIA

1. Does the patient have both the diagnoses of folate deficiency and vitamin B12 deficiency and meet **ALL** of the following criteria?
   - The patient has a serum folate < 2.0 ng/mL (below 4.5 nmol/L or below laboratory specific lower limit of normal is acceptable)
   - The patient has a serum vitamin B12 < 200 pg/mL (below 148 pmol/L or below laboratory specific lower limit of normal is acceptable)
   - The physician attests to the continued need for therapy due to a medical condition resulting in irreversible folate and vitamin B12 deficiency (e.g., pernicious anemia, gastric bypass surgery)

   If yes, **approve for 12 months by GPID (40914) with a quantity limit of #30 tablets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MULTIVIT34/FOLIC ACID/NADH/COQ10

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **MULTIVIT34/FOLIC ACID/NADH/COQ10 (Mebolic, Zyvit, Xyzbac)** requires the diagnosis of folate deficiency and vitamin B12 deficiency for renewal. In addition, the following criteria must be met:

- The patient has a serum folate < 2.0 ng/mL (below 4.5 nmol/L or below laboratory specific lower limit of normal is acceptable)
- The patient has a serum vitamin B12 < 200 pg/mL (below 148 pmol/L or below laboratory specific lower limit of normal is acceptable)
- The physician attests to the continued need for therapy due to a medical condition resulting in irreversible folate and vitamin B12 deficiency (e.g., pernicious anemia, gastric bypass surgery)

RATIONALE

Promote appropriate utilization of **MULTIVIT34/FOLIC ACID/NADH/COQ10** (Xyzbac, Mebolic, Zyvit) based on labeled uses and available treatment options.

DESCRIPTION

Mebolic, Zyvit and Xyzbac Tablets are orally administered prescription vitamin formulations for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

DOSAGE AND ADMINISTRATION

Usual adult dose is one tablet once or twice daily or as prescribed by a licensed medical practitioner.

DOSAGE FORMS

Oral Tablets. Available by Prescription.

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MULTIVIT34/FOLIC ACID/NADH/COQ10

DOSAGE FORMS

	Amount per tablet	Daily Value (DV)
Vitamin C (as ascorbic acid)	125 mg	208%
Vitamin D3 (as cholecalciferol)	500 IU	125%
Thiamin (Vitamin B1 as thiamin HCL)	25 mg	1,667%
Vitamin B6 (as pyridoxal 5' phosphate)	12.5 mg	625%
Folic Acid	1 mg	250%
Vitamin B12 (methylcobalamin)	1000 mcg	16,667%
NADH (reduced nicotinamide-adenine dinucleotide)	5 mg	not established
CoEnzyme Q-10 (ubiquinone)	50 mg	not established

REFERENCES

- Mebolic [Prescribing Information]. Madisonville, LA, USA Solubiomix,Inc.; September 2017
- Xyzbac [Prescribing Information]. Madisonville, LA, USA Solubiomix, Inc.; September 2017.
- Zyvit [Prescribing Information]. Murrieta, GA USA, TMIG Rx, Inc.; October 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/18

Created: 11/17
Client Approval: 12/17

P&T Approval: 10/17