MASSACHUSETTS

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Medical Policy

Serological Diagnosis of Celiac Disease

Table of Contents

Policy Number: 138

BCBSA Reference Number: 2.04.30A (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon #185

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Serologic measurement of tissue transglutaminase (TTG) or antiendomysial antibodies (EMA) may be considered **MEDICALLY NECESSARY** in individuals with signs or symptoms suggestive of celiac disease.

Serologic measurement of antigliadin antibodies may be considered **MEDICALLY NECESSARY** **in children less than 24 months of age** with signs or symptoms suggestive of celiac disease.

HLA-DQ2 and HLA-DQ8 testing may be considered **MEDICALLY NECESSARY** to rule out celiac disease in individuals with discordant serologic and histologic (biopsy) findings or if persistent symptoms warrant testing despite negative serology and histology.

Screening of asymptomatic at-risk patient groups for celiac disease using one or more serologic IgA or IgG measures is considered **INVESTIGATIONAL**.

Population screening for celiac disease using one or more serologic IgA or IgG measures is considered **INVESTIGATIONAL**.

Serologic measurement of deamidated gliadin peptide (DGP) antibodies is considered **MEDICALLY NECESSARY** in individuals with signs or symptoms suggestive of celiac disease.[1]

Serologic measurement of deamidated gliadin peptide antibodies is considered **INVESTIGATIONAL** in individuals **without** signs or symptoms suggestive of celiac disease.[1]

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
86364	Tissue transglutaminase
86258	Gliadin antibody

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D51.0	Vitamin B12 deficiency anemia due to intrinsic factor deficiency
D51.1	Vitamin B12 deficiency anemia due to selective vitamin B12 malabsorption with proteinuria
D51.3	Other dietary vitamin B12 deficiency anemia
D51.8	Other vitamin B12 deficiency anemias
D51.9	Vitamin B12 deficiency anemia, unspecified
D53.1	Other megaloblastic anemias, not elsewhere classified
D73.0	Hyposplenism
D80.2	Selective deficiency of immunoglobulin A [IgA]
E06.3	Autoimmune thyroiditis
E10.65	Type 1 diabetes mellitus with hyperglycemia

E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E30.0	Delayed puberty
E43	Unspecified severe protein-calorie malnutrition
E44.0	Moderate protein-calorie malnutrition
E44.1	Mild protein-calorie malnutrition
E46	Unspecified protein-calorie malnutrition
E55.9	Vitamin D deficiency, unspecified
E86.0	Dehydration
E88.09	Other disorders of plasma-protein metabolism, not elsewhere classified
F93.8	Other childhood emotional disorders
G11.10	Early-onset cerebellar ataxia, unspecified
G11.19	Other early-onset cerebellar ataxia
G11.2	Late-onset cerebellar ataxia
G40.B01	Juvenile myoclonic epilepsy, not intractable, with status epilepticus
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus
G40.B11	Juvenile myoclonic epilepsy, intractable, with status epilepticus
G40.B19	Juvenile myoclonic epilepsy, intractable, without status epilepticus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G62.9	Polyneuropathy, unspecified
G90.09	Other idiopathic peripheral autonomic neuropathy
J84.03	Idiopathic pulmonary hemosiderosis
K02.51	Dental caries on pit and fissure surface limited to enamel
K02.61	Dental caries on smooth surface limited to enamel
K12.0	Recurrent oral aphthae
K12.30	Oral mucositis (ulcerative), unspecified
K14.0	Glossitis
K14.4	Atrophy of tongue papillae
K20.0	Eosinophilic esophagitis
K21.00	Gastro-esophageal reflux disease with esophagitis, without bleeding
K21.01	Gastro-esophageal reflux disease with esophagitis, with bleeding
K21.9	Gastro-esophageal reflux disease without esophagitis
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications

K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K52.831	Collagenous colitis
K52.832	Lymphocytic colitis
K52.838	Other microscopic colitis
K52.839	Microscopic colitis, unspecified
K52.89	Other specified noninfective gastroenteritis and colitis
K52.9	Noninfective gastroenteritis and colitis, unspecified
K59.00	Constipation, unspecified
K75.4	Autoimmune hepatitis
K83.01	Primary sclerosing cholangitis
K90.3	Pancreatic steatorrhea
K90.41	Non-celiac gluten sensitivity
K90.49	Malabsorption due to intolerance, not elsewhere classified
L13.0	Dermatitis herpetiformis
M08.90	Juvenile arthritis, unspecified, unspecified site
M25.50	Pain in unspecified joint

M25.511	Pain in right shoulder
M25.512	Pain in left shoulder
M25.519	Pain in unspecified shoulder
M25.521	Pain in right elbow
M25.522	Pain in left elbow
M25.529	Pain in unspecified elbow
M25.531	Pain in right wrist
M25.532	Pain in left wrist
M25.539	Pain in unspecified wrist
M25.541	Pain in joints of right hand
M25.542	Pain in joints of left hand
M25.549	Pain in joints of unspecified hand
M25.551	Pain in right hip
M25.552	Pain in left hip
M25.559	Pain in unspecified hip
M25.561	Pain in right knee
M25.562	Pain in left knee
M25.569	Pain in unspecified knee
M25.571	Pain in right ankle and joints of right foot
M25.572	Pain in left ankle and joints of left foot
M25.579	Pain in unspecified ankle and joints of unspecified foot
M25.59	Pain in other specified joint
M62.5	Muscle wasting and atrophy, not elsewhere classified
M81.6	Localized osteoporosis [Lequesne]
M81.8	Other osteoporosis without current pathological fracture
M83.2	Adult osteomalacia due to malabsorption
M83.3	Adult osteomalacia due to malnutrition
M83.8	Other adult osteomalacia
M83.9	Adult osteomalacia, unspecified
N46.9	Male infertility, unspecified
N91.2	Amenorrhea, unspecified
N97.9	Female infertility, unspecified
P94.2	Congenital hypotonia
Q90.9	Down syndrome, unspecified
Q93.82	Williams syndrome
Q96.8	Other variants of Turner's syndrome
Q96.9	Turner's syndrome, unspecified
R10.0	Acute abdomen
R10.10	Upper abdominal pain, unspecified
R10.11	Right upper quadrant pain
R10.12	Left upper quadrant pain
R10.13	Epigastric pain
R10.2	Pelvic and perineal pain
R10.30	Lower abdominal pain, unspecified
R10.31	Right lower quadrant pain
R10.32	Left lower quadrant pain
R10.33	Periumbilical pain
R10.84	Generalized abdominal pain
R10.9	Unspecified abdominal pain
R11.0	Nausea

R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.2	Nausea with vomiting, unspecified
R14.0	Abdominal distension (gaseous)
R14.1	Gas pain
R14.2	Eructation
R14.3	Flatulence
R19.4	Change in bowel habit
R19.5	Other fecal abnormalities
R19.7	Diarrhea, unspecified
R19.8	Other specified symptoms and signs involving the digestive system and abdomen
R21	Rash and other nonspecific skin eruption
R23.8	Other skin changes
R23.9	Unspecified skin changes
R27.0	Ataxia, unspecified
R27.8	Other lack of coordination
R27.9	Unspecified lack of coordination
R45.4	Irritability and anger (child)
R51.9	Headache, unspecified
R53.1	Weakness
R53.8	Other malaise and fatigue
R53.81	Other malaise
R53.83	Other fatigue
R60.0	Localized edema
R60.1	Generalized edema
R60.9	Edema, unspecified
R62.51	Failure to thrive (child)
R62.52	Short stature (child)
R63.0	Anorexia
R63.4	Abnormal weight loss
R74.01	Elevation of levels of liver transaminase levels
Z83.79	Family history of other diseases of the digestive system

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
86231	Endomysial antibody

Description

Celiac disease, which may be referred to as celiac sprue or gluten-sensitive enteropathy, is defined as inflammation of the small intestine resulting from an immunologic intolerance to gluten (i.e., the proteins derived from wheat, barley, and rye). The diagnosis criteria reflects a positive biopsy at presentation, in conjunction with consistent history and serologic results, followed by a clinical response to a gluten-free diet, and relapse when dietary gluten is reintroduced.

Clinical symptoms are variable, nonspecific, and are often overlooked. In addition, the disease may develop at any time in life, from infancy to very old age. While a positive biopsy result is considered the gold standard for diagnosis, serologic evaluation of individuals with possible celiac disease can be used to triage the large numbers of individuals with nonspecific symptoms for biopsy.

Serologic diagnosis is focused on the detection of IgA antibodies, such as **antigliadin**, **antiendomysial,** and **tissue transglutaminase**. **Antigliadin antibodies (AGA)** can be detected using an enzyme-linked immunosorbent assay (ELISA) test. Another serologic study is to test for the presence of antiendomysial antibodies (EMA) also with an ELISA-based test, and a dot blot procedure that can be performed in the physician's office.

Deamidated gliadin peptide (DGP) antibody tests are the newest tests for celiac disease. Individuals have elevated levels of these antibodies if the celiac disease is untreated. The test measures levels of deamidated gliadin antibodies in the blood and if elevated it is indicative of celiac disease. The small intestine may be damaged, and malnutrition may occur in undiagnosed individuals. The test may be requested as deamidated gliadin peptide antibodies, DGP, DGP-AGA, or DGP IgA and IgG. The testing method is enzyme-linked immunosorbent assay, and the specimen is serum.

deamidated gliadin peptide (DGP) antibodies (anti-DGP), IgA or IgG may also be requested in individuals with suspected celiac disease who are negative for anti-TTG, especially children younger than 2 years old.

Examples of antibody testing for celiac disease are widely available from laboratories such as Quest, LabCorp, and Prometheus. All antibody tests for celiac disease are considered investigational regardless of the commercial name, the manufacturer or FDA approval status, except when used for the medically necessary indications that are consistent with the policy statement.

Summary

Tissue Transglutaminase (TTG) and Antiendomysial Antibody (EMA)
Use of serology tests, if accurate, reduce the need for multiple biopsies. Evidence from systematic reviews and head-to-head comparative studies using biopsy as the gold standard conclude there is sufficient evidence that tissue transglutaminase and antiendomysial antibody tests are reasonably accurate for identifying celiac disease in individuals with signs or symptoms of the disease. One study found that in children under 18 months old, serologic measurement of antigliadin antibodies is more sensitive than either of the other 2 tests. For these reasons, these tests for the defined population may be considered medically necessary.

Deamidated Gliadin Peptide (DGP) Antibody
Evidence from a systemic review and meta-analysis evaluated by head-to-head comparison the diagnostic accuracy of TTG IgA and DGP IgG antibodies and concluded that TTG IgA specificity was significantly higher while the sensitivity of DGP IgG was higher. The authors concluded that both meta-analysis and the systematic review showed that some children with early celiac disease were missed without the DGP IgG test. While TTG IgA is the best celiac disease test in **children <2 years of age**, the study noted that the addition of DGP IgG may increase the diagnostic sensitivity. Catassi 2021

TTG-IgA antibody was compared with the deamidated gliadin peptide (DGP), of both IgG (DGP-IgG) and IgA (DGP-IgA) types, in individuals with celiac disease. The study included individuals with a median age of **15 years (range, 5-18 years)**. The authors found good correlation between TTG-IgA and DGP-IgG and TTG-IgA and DGP-IgA, and substantial agreement between TTG-IgA and DGP-IgG, but moderate agreement between TTG-IgA and DGP-IgA. The results indicated that DGP-IgG was comparable to TTG-IgA and may be useful as an alternative to TTG-IgA in the diagnosis and follow-up of individuals with celiac disease. Saadah OI 2020

This study compared the performance of IgA anti-tissue transglutaminase antibodies (IgA anti-TTG), IgA anti-endomysial antibodies (IgA EMA), and IgA/IgG antibodies against deamidated gliadin peptides (IgA/IgG anti-DGP) for the diagnosis of celiac disease. A total of 136 children were included with a **median age of 78.4 months old**. The authors concluded that IgA EMA, IgA anti-TTG, and IgG anti-DGP antibodies showed adequate specificity and sensitivity. The IgG anti-DGP/anti-TTG combination showed

a 98-99 % sensitivity and a 100 % specificity. The anti-TTG and IgG anti-DGP option yields excellent results, with a low cost and independence from the observer. Ortiz G 2019.

This retrospective review (n=478) included **children 3 years old and under**, who had DGP and/or TTG serologies along with duodenal biopsies during their initial diagnostic evaluation. The authors reported that the positive predictive value (PPV) of the DGP-IgA test was 91.7% while DGP-IgG was 77.8%. When DGP serology was examined in conjunction with TTG-IgA, the PPV with DGP-IgA was 90.9% and with DGP-IgG was 87.5%. The study concluded that DGP-IgA provides high PPV and specificity for celiac in children younger than 3 years old while DGP-IgG showed lower PPV in this age group. When used alone or in conjunction with TTG-IgA, the DGP-IgA test results in a high PPV of 91.7 and 90.9%. This study recommended obtaining both the DGP-IgA and the TTG-IgA serology when screening infants and children younger than 3 years old for celiac disease. Leonard-Puppa 2021.

Pediatric Celiac Disease: A Review of Diagnostic Testing and Guideline

- **For children under 2 years of age**, the guidelines suggest that anti-DGP assays may be preferable to anti-TTG and that a biopsy was still recommended in these situations.
- This newer guideline puts even more focus on TTG-IgA testing, recommending that this test be used for all children regardless of age and citing that anti-DGP may have lower specificity in younger children. Horton RK 2022.

This prospective study **(n=141 adult individuals)** showed that anti-DGP tests are accurate markers of celiac disease. The combinations of 2 tests, IgG a-DGP plus IgA a-TTG or the single blended conjugate detecting IgA + IgG a-DGP plus IgA a-TTG had 100% positive and negative predictive values. The authors concluded that a-DGP test, alone or in combination with the more commonly used a-TTG test, can potentially be used in many cases to avoid intestinal biopsy, thus having an impact on cost savings and better acceptance by individuals. Niveloni 2007

Based on the studies noted above, there is sufficient evidence that deamidated gliadin peptide (DGP) tests may be considered medically necessary in individuals with signs or symptoms suggestive of celiac disease.

There is insufficient evidence that measurement of DGP antibodies in asymptomatic individuals or population screening improves the net health outcome of asymptomatic individuals. On March 28, 2017, the USPSTF concluded that current evidence is insufficient to assess the balance of benefits and harms of screening for celiac disease in asymptomatic individuals.

Policy History

Date	Action
9/2022	Annual policy review. Policy updated with literature review through September 2022. No references added. Policy statements unchanged.
8/2022	Annual policy review. Policy revised to include coverage for serologic measurement of deamidated gliadin peptide (DGP) antibodies. Clarified coding information. Effective 8/1/2022.
1/2022	Clarified coding information.
2/2020	Policy updated with literature review through February 1, 2020. No references added. Policy statements unchanged.
2/2013	Annual policy review. New references added.
2/2013	Annual policy review. Changes made to policy statement.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition/ Organ Transplantation No changes to policy statements.
9/1/2011	Annual policy review. Policy revised to include a new policy statement stating that serologic measurement of deamidated gliadin peptide antibodies is investigational.

11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition/ Organ Transplantation No changes to policy statements.
11/01/2009	New policy. Effective 11/01/2009.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion