Policy Name: Human Leukocyte Antigen-DQ (HLA-DQ) Genetic Testing for Celiac Disease
Effective Date: 4/19/2017

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
HLA-DQ genetic testing for celiac disease is COVERED.

Description
HLA-DQ genetic testing for celiac disease is a laboratory test performed on a blood sample to evaluate genetic variants associated with celiac disease. HLA-DQ genotyping is performed to detect variants of HLA-DQ Alpha 1 and HLA-DQ Beta 1, which are located on chromosome 6 at band p21.3.

Celiac disease is classified as a multifactorial systemic autoimmune disorder, with environmental as well as HLA and non-HLA genetic components. Studies indicate that prevalence of celiac disease among healthy individuals in the United States currently ranges from one out of 120-300 individuals, rising to one in 56 among individuals with celiac-related symptoms. Celiac disease may be associated with various gastrointestinal symptoms (e.g., diarrhea, weight loss, lactose intolerance, abdominal distention/discomfort) or non-gastrointestinal characteristics (e.g., joint pain/inflammation, iron-deficiency anemia, vitamin deficiency, osteoporosis/osteopenia).

The diagnosis of celiac disease has historically relied on serological antibody testing (e.g., tissue transglutaminase IgA, endomysial antibody IgA, anti-deamminated gliadin-related peptide antibodies IgG and IgA, total IgA), defined histological findings upon small-bowel biopsy, and/or histological improvement seen on biopsy following adherence to a gluten free diet. Since 30% - 40% of the general population carries one of the celiac disease-associated HLA alleles and only 3% develop celiac disease, the presence of celiac disease-associated HLA alleles is not in itself diagnostic of celiac disease. However, absence of these alleles essentially excludes a diagnosis of celiac disease.

FDA Approval
Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and the assay is not marketed for general use.
Laboratories in the United States that offer genetic testing for diagnosis of celiac disease include, but may not be limited to:

1. ARUP Laboratories
2. Enterolab
3. Laboratory Corporation of America (LabCorp)
4. Quest Diagnostics
5. Mayo Clinic Laboratories
6. Prometheus Therapeutics & Diagnostics

Prior Authorization
Prior authorization is not applicable.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes
- 81370 - HLA Class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1
- 81375 - HLA Class II typing, low resolution (eg, antigen equivalents); HLA-DRB1/3/4/5 and -DQB1
- 81376 - HLA Class II typing, low resolution (eg, antigen equivalents); 1 locus (eg, HLA-DRB1/3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
- 81377 - HLA Class II typing, low resolution (eg, antigen equivalents); 1 antigen equivalent, each
- 81382 - HLA Class II typing, high resolution (ie, alleles or allele groups); 1 locus (eg, HLA-DRB1, -DRB3, -DRB4, -DRB5, -DQB1, -DQA1, -DPB1, or -DPA1), each
- 81383 - HLA Class II typing, high resolution (ie, alleles or allele groups); 1 allele or allele group (eg, HLA-DQB1*06:02P), each
- 89240 - Unlisted miscellaneous pathology test

Original Effective Date: 1/1/2012

Re-Review Date(s): 4/19/2017
2/17/2020 – administrative update; format