If a conflict arises between a Clinical Payment and Coding Policy ("CPCP") and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSNM may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSNM has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act ("HIPAA") approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing ("UB") Editor, American Medical Association ("AMA"), Current Procedural Terminology ("CPT®"), CPT® Assistant, Healthcare Common Procedure Coding System ("HCPCS"), ICD-10 CM and PCS, National Drug Codes ("NDC"), Diagnosis Related Group ("DRG") guidelines, Centers for Medicare and Medicaid Services ("CMS") National Correct Coding Initiative ("NCCI") Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Celiac Disease Testing

Policy Number: CPCPLAB017

Version 1.0

Enterprise Medical Policy Committee Approval Date: 1/25/2022

Plan Effective Date: May 1, 2022

Description

BCBSNM has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

1. Serologic testing for the diagnosis of celiac disease **may be reimbursable** with the IgA anti-tissue transglutaminase (TTG) and the total IgA test for individuals with signs and symptoms of celiac disease **(See Note** 1).

2. Testing for IgA endomysial antibodies **may be reimbursable** in individuals at risk for celiac disease (**See Note 1**) when IgA anti-TTG is negative or weakly positive.

3. Testing for IgG endomysial antibodies, IgG deamidated gliadin peptide, or IgG TTG **may be reimbursable** in individuals with clinical suspicion of celiac disease, (**See Note 1**), with an IgA deficiency.

4. Testing for IgA and IgG antibodies to deamidated gliadin peptides **may be reimbursable** for the diagnosis of celiac disease in children under 2 years of age with a clinical suspicion of celiac disease (**See Note 1**) and in those over 2 years of age as a substitute for anti-TTG testing.

5. Genetic testing for HLA DQ2 and DQ8 **may be reimbursable** for:
    a. Symptomatic individuals for whom other testing is undiagnostic; or
    b. Symptomatic individuals with positive serology tests who are unable to undergo biopsy evaluation.

6. Biopsy of the small intestine **may be reimbursable** for confirmation of celiac disease for individuals at high risk for celiac disease regardless of the result of celiac disease serology testing.

7. Rapid antigen point-of-care testing for anti-TTG **is not reimbursable.**

8. Panel testing, multiplex, or multi-analyte testing (for more than two analytes) for the diagnosis or the evaluation of celiac disease **is not reimbursable**.

9. Testing for anti-reticulin antibodies **is not reimbursable** for the diagnosis of celiac disease.

10. Testing of stool or saliva samples for the evaluation of celiac disease **is not reimbursable**.

11. Serologic testing using an HLA-DQ-gluten tetramer-based assay, including flow cytometry-based HLA-DQ-gluten tetramer assays, **is not reimbursable.**

NOTE 1: Signs and symptoms of celiac disease may include, but are not limited to, the following: unexplained chronic or intermittent diarrhea; unexplained weight loss; unexplained chronic or intermittent abdominal pain or bloating; recurrent nausea or vomiting; unexplained iron deficiency anemia; unexplained vitamin B12 or folate deficiency; unexplained liver transaminase elevations; autoimmune hepatitis; dermatitis herpetiformis; type 1 diabetes; intestinal blockages; unexplained subfertility or miscarriage; unexplained osteoporosis, osteomalacia, or low bone density; and/or primary biliary cirrhosis. Individuals with Down syndrome, Turner syndrome, or Willams-Beuren syndrome are also at high risk for celiac disease. Additionally, in pediatric patients, fatty stools, delayed puberty, amenorrhea, failure to thrive, stunted growth, and/or short stature may also be associated with celiac disease (Husby et al., 2020; NICE, 2020; NIDDK, 2016).

Procedure Codes

Codes
81376, 81377, 81382, 81383, 82784, 83516, 86255, 86256, 86828, 86829, 86831, 86833, 86835, 88305, 88346, 88350

References:

Al-Toma, A., Volta, U., Auricchio, R., Castillejo, G., Sanders, D. S., Cellier, C., . . . Lundin, K. E. A. (2019). European Society for the Study of Coeliac Disease (ESsCD) guideline for coeliac disease and other gluten-related disorders. *United European Gastroenterol J, 7*(5), 583-613. doi:10.1177/2050640619844125

Arenda. (2020). SIMTOMAX DGP TEST. Retrieved from https://www.arenda.hr/en/simtomax-dgp-test.aspx

Bai, J. C., & Ciacci, C. (2017). World Gastroenterology Organisation Global Guidelines: Celiac Disease February 2017. *J Clin Gastroenterol, 51*(9), 755-768. doi:10.1097/mcg.0000000000000919

Bajor, J., Szakács, Z., Farkas, N., Hegyi, P., Illés, A., Solymár, M., . . . Vincze, Á. (2019). Classical celiac disease is more frequent with a double dose of HLA-DQB1*02: A systematic review with meta-analysis. *PLoS One, 14*(2), e0212329. doi:10.1371/journal.pone.0212329

Bibbins-Domingo, K., Grossman, D. C., Curry, S. J., Barry, M. J., Davidson, K. W., Doubeni, C. A., . . . Tseng, C. W. (2017). Screening for Celiac Disease: US Preventive Services Task Force Recommendation Statement. *Jama, 317*(12), 1252-1257. doi:10.1001/jama.2017.1462

Brown, N. K., Guandalini, S., Semrad, C., & Kupfer, S. S. (2019). A Clinician's Guide to Celiac Disease HLA Genetics. *Am J Gastroenterol, 114*(10), 1587-1592. doi:10.14309/ajg.0000000000000310

Bufler, P., Heilig, G., Ossiander, G., Freudenberg, F., Grote, V., & Koletzko, S. (2015). Diagnostic performance of three serologic tests in childhood celiac disease. *Z Gastroenterol, 53*(2), 108-114. doi:10.1055/s-0034-1385704

Caio, G., Volta, U., Sapone, A., Leffler, D. A., De Giorgio, R., Catassi, C., & Fasano, A. (2019). Celiac disease: a comprehensive current review. *BMC Med, 17*(1), 142. doi:10.1186/s12916-019-1380-z

CDF. (2018). What is Celiac disease? Retrieved from https://celiac.org/celiac-disease/understanding-celiac-disease-2/what-is-celiac-disease/

FDA. (2014). IG_PLEX CELIAC DGP PANEL. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K140691

FDA. (2017). DECISION SUMMARY. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160026.pdf

FDA. (2021a). Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

FDA. (2021b, June 16). Aptiva Celiac Disease IgA Reagent. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/reviews/K193604.pdf

Gould, M. J., Mahmud, F. H., Clarke, A. B. M., McDonald, C., Saibil, F., Punthakee, Z., & Marcon, M. A. (2021). Accuracy of Screening Tests for Celiac Disease in Asymptomatic Patients With Type 1 Diabetes. *Am J Gastroenterol, 116*(7), 1545-1549. doi:10.14309/ajg.0000000000001193

Hill, I. D., Fasano, A., Guandalini, S., Hoffenberg, E., Levy, J., Reilly, N., & Verma, R. (2016). NASPGHAN Clinical Report on the Diagnosis and Treatment of Gluten-related Disorders. *J Pediatr Gastroenterol Nutr, 63*(1), 156-165. doi:10.1097/mpg.0000000000001216

Husby, S., Koletzko, S., Korponay-Szabó, I., Kurppa, K., Mearin, M. L., Ribes-Koninckx, C., . . . Wessels, M. (2020). European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Coeliac Disease 2020. *J Pediatr Gastroenterol Nutr, 70*(1), 141-156. doi:10.1097/mpg.0000000000002497

Husby, S., Koletzko, S., Korponay-Szabó, I. R., Mearin, M. L., Phillips, A., Shamir, R., . . . for the ESPGHAN Working Group on Coeliac Disease Diagnosis, o. b. o. t. E. G. C. (2012). European Society for Pediatric Gastroenterology, Hepatology, and Nutrition Guidelines for the Diagnosis of Coeliac Disease. *J Pediatr Gastroenterol Nutr, 54*(1), 136-160. doi:10.1097/MPG.0b013e31821a23d0

Husby, S., Murray, J. A., & Katzka, D. A. (2019). AGA Clinical Practice Update on Diagnosis and Monitoring of Celiac Disease—Changing Utility of Serology and Histologic Measures: Expert Review. *Gastroenterology, 156*(4), 885-889. doi:10.1053/j.gastro.2018.12.010

Jansson-Knodell, C. L., Hujoel, I. A., West, C. P., Taneja, V., Prokop, L. J., Rubio-Tapia, A., & Murray, J. A. (2019). Sex Difference in Celiac Disease in Undiagnosed Populations: A Systematic Review and Meta-analysis. *Clin Gastroenterol Hepatol, 17*(10), 1954-1968.e1913. doi:10.1016/j.cgh.2018.11.013

Kelly, C. P. (2021, March 4). Diagnosis of celiac disease in adults. *UpToDate.* Retrieved from https://www.uptodate.com/contents/diagnosis-of-celiac-disease-in-adults

Ludvigsson, J. F., Bai, J. C., Biagi, F., Card, T. R., Ciacci, C., Ciclitira, P. J., . . . Sanders, D. S. (2014). Diagnosis and management of adult coeliac disease: guidelines from the British Society of Gastroenterology. *Gut, 63*(8), 1210-1228. doi:10.1136/gutjnl-2013-306578

Mubarak, A., Spierings, E., Wolters, V., van Hoogstraten, I., Kneepkens, C. M., & Houwen, R. (2013). Human leukocyte antigen DQ2.2 and celiac disease. *J Pediatr Gastroenterol Nutr, 56*(4), 428-430. doi:10.1097/MPG.0b013e31827913f9

Murch, S., Jenkins, H., Auth, M., Bremner, R., Butt, A., France, S., . . . Thorpe, M. (2013). Joint BSPGHAN and Coeliac UK guidelines for the diagnosis and management of coeliac disease in children. *Arch Dis Child, 98*(10), 806-811. doi:10.1136/archdischild-2013-303996

NASSCD. (2017, October). Adult Guideline - Celiac Disease Diagnosis. Retrieved from https://www.theceliacsociety.org/cd-adult_diagnosis_guide

Nellikkal, S. S., Hafed, Y., Larson, J. J., Murray, J. A., & Absah, I. (2019). High Prevalence of Celiac Disease Among Screened First-Degree Relatives. *Mayo Clin Proc, 94*(9), 1807-1813. doi:10.1016/j.mayocp.2019.03.027

NICE. (2015, 09/02/2015). Coeliac disease: recognition, assessment and management. *National Guideline.* Retrieved from https://www.nice.org.uk/guidance/ng20/resources/coeliac-disease-recognition-assessment-and-management-pdf-1837325178565

NICE. (2016, 10/19/2016). Coeliac disease. *Quality Standards.* Retrieved from https://www.nice.org.uk/guidance/qs134/resources/coeliac-disease-pdf-75545419042501

NICE. (2020). Coeliac disease overview. Retrieved from https://pathways.nice.org.uk/pathways/coeliac-disease

NIDDK. (2016, 06/2016). Symptoms & Causes of Celiac Disease. Retrieved from https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease/symptoms-causes

NIDDK. (2020, October). Definition & Facts for Celiac Disease. Retrieved from https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease/definition-facts

Olen, O., Gudjonsdottir, A. H., Browaldh, L., Hessami, M., Elvin, K., Liedberg, A. S., . . . Grahnquist, L. (2012). Antibodies against deamidated gliadin peptides and tissue transglutaminase for diagnosis of pediatric celiac disease. *J Pediatr Gastroenterol Nutr, 55*(6), 695-700. doi:10.1097/MPG.0b013e3182645c54

Paul, S. P., Hoghton, M., & Sandhu, B. (2017). Limited role of HLA DQ2/8 genotyping in diagnosing coeliac disease. *Scott Med J, 62*(1), 25-27. doi:10.1177/0036933016689008

Pelkowski, T. D., & Viera, A. J. (2014). Celiac disease: diagnosis and management. *Am Fam Physician, 89*(2), 99-105.

Profaizer, T., Pole, A., Monds, C., Delgado, J. C., & Lázár-Molnár, E. (2020). Clinical utility of next generation sequencing based HLA typing for disease association and pharmacogenetic testing. *Hum Immunol, 81*(7), 354-360. doi:10.1016/j.humimm.2020.05.001

Rubio-Tapia, A., Hill, I. D., Kelly, C. P., Calderwood, A. H., & Murray, J. A. (2013). ACG clinical guidelines: diagnosis and management of celiac disease. *Am J Gastroenterol, 108*(5), 656-676; quiz 677. doi:10.1038/ajg.2013.79

Sakly, W., Mankai, A., Ghdess, A., Achour, A., Thabet, Y., & Ghedira, I. (2012). Performance of anti-deamidated gliadin peptides antibodies in celiac disease diagnosis. *Clin Res Hepatol Gastroenterol, 36*(6), 598-603. doi:10.1016/j.clinre.2012.01.008

Sarna, V. K., Lundin, K. E. A., Morkrid, L., Qiao, S. W., Sollid, L. M., & Christophersen, A. (2018). HLA-DQ-Gluten Tetramer Blood Test Accurately Identifies Patients With and Without Celiac Disease in Absence of Gluten Consumption. *Gastroenterology, 154*(4), 886-896.e886. doi:10.1053/j.gastro.2017.11.006

Selleski, N., Almeida, L. M., Almeida, F. C., Pratesi, C. B., Nobrega, Y. K. M., & Gandolfi, L. (2018). PREVALENCE OF CELIAC DISEASE PREDISPOSING GENOTYPES, INCLUDING HLA-DQ2.2 VARIANT, IN BRAZILIAN CHILDREN. *Arq Gastroenterol, 55*(1), 82-85. doi:10.1590/s0004-2803.201800000-16

Silvester, J. A., Kurada, S., Szwajcer, A., Kelly, C. P., Leffler, D. A., & Duerksen, D. R. (2017). Tests for Serum Transglutaminase and Endomysial Antibodies Do Not Detect Most Patients With Celiac Disease and Persistent Villous Atrophy on Gluten-free Diets: a Meta-analysis. *Gastroenterology, 153*(3), 689-701.e681. doi:10.1053/j.gastro.2017.05.015

Stankovic, B., Radlovic, N., Lekovic, Z., Ristic, D., Radlovic, V., Nikcevic, G., . . . Zukic, B. (2014). HLA genotyping in pediatric celiac disease patients. *Bosn J Basic Med Sci, 14*(3), 171-176. doi:10.17305/bjbms.2014.3.28

Tangermann, P., Branchi, F., Itzlinger, A., Aschenbeck, J., Schubert, S., Maul, J., . . . Schumann, M. (2019). Low Sensitivity of Simtomax Point of Care Test in Detection of Celiac Disease in a Prospective Multicenter Study. *Clin Gastroenterol Hepatol, 17*(9), 1780-1787.e1785. doi:10.1016/j.cgh.2018.09.032

TrueHealth. (2019). Celiac Disease and Gluten Sensitivity Testing. Retrieved from https://truehealthdiag.com/services/gluten/#av_section_4

Tye-Din, J. A., Galipeau, H. J., & Agardh, D. (2018). Celiac Disease: A Review of Current Concepts in Pathogenesis, Prevention, and Novel Therapies. *Front Pediatr, 6*, 350. doi:10.3389/fped.2018.00350

Vijzelaar, R., van der Zwan, E., van Gammeren, A., Yilmaz, R., Verheul, A., van Hoogstraten, I., . . . Kortlandt, W. (2016). Rapid Detection of the Three Celiac Disease Risk Genotypes HLA-DQ2.2, HLA-DQ2.5, and HLA-DQ8 by Multiplex Ligation-Dependent Probe Amplification. *Genet Test Mol Biomarkers, 20*(3), 158-161. doi:10.1089/gtmb.2015.0233

Policy Update History:

5/1/2022	New policy