Quantose Impaired Glucose Tolerance (IGT) Test AHS - G2135

Description of Procedure or Service

Quantose Glucose Tolerance Test is a laboratory test developed by Metabolon (Metabolon, 2017). According to Metabolon’s website (2017), “QUANTOSE™ IGT reflects the degree of impaired glucose tolerance in an individual. Impaired glucose tolerance (IGT) is a known risk factor for prediabetes. Our test is designed to easily differentiate IGT from normal glucose tolerance with only a single, fasted blood draw.”

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Quantose impaired glucose tolerance (IGT) test is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member’s Benefit Booklet for availability of benefits. Member’s benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Quantose Impaired Glucose Tolerance (IGT) Test is covered

Not applicable.

When Quantose Impaired Glucose Tolerance (IGT) Test is not covered

Quantose Impaired Glucose Tolerance (IGT) Test is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

A glucose tolerance test is completed to assess an individual’s response to glucose and the rate which it clears from the blood, and is used to diagnose diabetes, risk for prediabetes, or gestational diabetes. Blood samples are drawn at timed intervals to assess glucose values.

Cobb et al (2013) used the data from the Relationship between Insulin Sensitivity and Cardiovascular Disease (RISC) Study to generate and validate the Quantose test. The data from RISC, which was a prospective, observational, cohort study, were used in an iterative process to develop the algorithm.
1,277 subjects from the RISC study were divided into a training set and a test set for algorithm development and validation. A total of 26 metabolites from this study were collated and investigated for potential inclusion into an insulin resistance algorithm along with body mass index (BMI) and insulin. The investigators concluded that the Quantose test had clinical utility in the prediction of progression from normal glucose tolerance to impaired glucose tolerance and is superior to other simple baseline measures (fasting insulin, BMI, fasting glucose, HOMA-IR) in this regard. They further stated that the test may have value as an earlier predictor of prediabetes or Type 2 Diabetes Mellitus risk when compared with these traditional glycemic markers. The authors declared the potential conflicts of interest with respect to the research, authorship and/or publication of this article. The study was funded by Metabolon Inc. and 10 of the 13 authors of the study were full-time employees of Metabolon Inc.

Tripathy et al (2015) “examined the clinical utility of Quantose M(Q) to monitor changes in insulin sensitivity after pioglitazone therapy in prediabetic subjects. Participants were 428 of the total of 602 ACT NOW impaired glucose tolerance (IGT) subjects randomized to pioglitazone (45 mg/d) or placebo and followed for 2.4 years. At baseline and study end, fasting plasma metabolites required for determination of Quantose, glycated hemoglobin, and oral glucose tolerance test with frequent plasma insulin and glucose measurements to calculate the Matsuda index of insulin sensitivity were obtained. In logistic models including only anthropometric and fasting measurements, Quantose M(Q) outperformed both Matsuda and fasting insulin in predicting incident diabetes.”

**Applicable Federal Regulations**
This test is considered a laboratory developed test (LDT); developed, validated and performed by individual laboratories.

LDTs are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA’88).

As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

**Billing/Coding/Physician Documentation Information**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 84999*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

**Scientific Background and Reference Sources**


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Specialty Matched Consultant Advisory Panel review 2/2020

Policy Implementation/Update Information

1/1/2019 New policy developed. Quantose impaired glucose tolerance (IGT) test is considered investigational. Medical Director review 1/1/2019. Policy noticed 1/1/2019 for effective date 4/1/2019. (lpr)

8/27/19 Removed coding table from Billing/Coding section per Avalon Q2 CAB 2019. No changes to policy statement. (lpr)

03/10/20 Specialty Matched Consultant Advisory Panel review 2/19/2020. No change to policy statement. (eel)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.