



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Home Hemoglobin Testing Devices

Effective Date 7/15/2011
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Coverage Policy Number 0389

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Hyperlink to Related Coverage Policies

Diabetic Supplies
Home Blood Glucose Monitors
Prothrombin Time Home Testing Systems

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA does not cover the use of a home hemoglobin testing device for any indication because its use is considered experimental, investigational or unproven.

General Background

Home hemoglobin testing has been proposed for patients with chronic anemia to potentially monitor variations in hemoglobin levels and facilitate medication adjustments by healthcare providers as needed. Although other parameters are examined in the work-up of anemia, the hemoglobin count is the most useful indicator of anemia because it determines the oxygen-carrying capacity of the blood. Symptoms of anemia depend on the etiology, but commonly include fatigue, muscle weakness, shortness of breath, rapid heart beat, and pale skin. Treatment for anemia is based on the underlying cause, but usually involves dietary changes, nutritional supplements, and medications such as epoetin for patients with chronic kidney disease or cancer-related anemia. In severe cases of anemia, blood transfusions may be necessary.

The reference standard for hemoglobin testing is venous blood processed by a laboratory using the Coulter cell-counting system. The emergence of point-of-care (POC) testing has allowed for immediate access to laboratory results and faster decision-making regarding patient care. A number of portable POC hematology analyzers are in use in clinical settings such as physicians' offices, dialysis units and blood donation centers. These devices can measure a variety of laboratory values, including hemoglobin, hematocrit, glucose, red or white blood cells,

chemistries and coagulation. POC devices are currently approved only for bedside or office-based use by a healthcare professional.

U.S. Food and Drug Administration (FDA)

POC hemoglobin analyzers such as the CELL-DYN® 1200 System multi-parameter hematology analyzer (Abbott Laboratories, Santa Clara, CA) and the ITC Hgb Pro Professional Hemoglobin Testing System™ (International Technidyne Corp., Edison, NJ), were approved as Class II devices under the 510(k) process because they were found to be substantially equivalent to the HemoCue B-Hemoglobin Photometer. The HemoCue B-Hemoglobin Photometer (HemoCue, Inc., Potomac, MD) was granted waived status under the Clinical Laboratory Improvement Amendments (CLIA) in 1993. The device received FDA approval based on validation studies submitted by the manufacturer. These studies indicated that the accuracy of the HemoCue was equivalent to results provided by the standard laboratory Coulter system. These devices were all developed to be used by trained healthcare providers in a clinical setting. None of the above-mentioned devices are FDA approved for patient self-monitoring.

The AnemiaPro™ Self-Screener Hemoglobin Test Kit system (Ortho Biotech Products, L.P., Bridgewater, NJ), was granted marketing approval by the FDA via the 510(k) process on January 11, 2005. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the AnemiaPro™ prior to marketing the device. However, data submitted by the manufacturer with the request for approval reported an overall sensitivity of 96.4% and specificity of 97.7% for this device. These data were generated in a series of comparison studies in which the AnemiaPro™ was compared to CELL-DYN® and HemoCue devices. The studies included a total of 267 “untrained lay user participants.” Information as to the setting of these studies was not available (FDA, 2005). According to the FDA, the AnemiaPro is intended for over-the-counter (OTC) distribution and is indicated for the determination of hemoglobin concentration in a self-collected whole blood sample. The device is not intended for use in neonates.

Literature Review

A number of validation studies have documented the diagnostic precision and accuracy of the various POC hematology analyzers. The HemoCue predicate device is the most studied of the hemoglobin analyzers. Sensitivity and specificity have been consistently reported to be greater than 90% in controlled clinical settings (Neufeld, et al., 2002; Teli, et al., 2002; Lardi, et al., 1999). There is some question as to the reliability or within subject variability of this testing method, particularly in samples of capillary origin. It has been recommended that replicate sampling be used to reduce the influence of unreliability (Morris, et al., 1999). No studies were identified that have evaluated self-monitoring of hemoglobin levels in the home setting.

Summary

While point-of-care (POC) devices for hematological testing are widely used in a number of clinical settings, the efficacy of such testing in the home setting has not been studied. There is a lack of evidence in the published, peer-reviewed medical literature demonstrating that patient self-monitoring can lead to improved health outcomes for the management of chronic anemia. The clinical utility of home hemoglobin testing compared to POC hematological testing has not been established.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered when used to report home hemoglobin testing devices:

HCPSC Codes	Description
E1399	Durable medical equipment, miscellaneous

ICD-9-CM Diagnosis Codes	Description
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281.0-280.9	Iron deficiency anemias
281.0-281.9	Other deficiency anemias
282.0-282.9	Hereditary hemolytic anemias
283.0-283.9	Acquired hemolytic anemias
284.01-284.9	Aplastic anemia and other bone marrow failure syndromes
285.0-285.9	Other and unspecified anemias

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	7/15/2008	0389	Home Hemoglobin Testing Devices

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