Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Galectin-3 has been investigated as an in vitro test that quantitatively measures galectin-3 serum or EDTA-plasma to be used in clinical evaluation as an aid in assessing the prognosis of individuals diagnosed with chronic heart failure.
LABORATORY TESTING FOR GALECTIN-3 (cont.)

Criteria:

- Laboratory testing for galectin-3 is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These laboratory tests or assays include, but are not limited to:

- BGM Galectin-3®

Resources:


LABORATORY TESTING FOR GALECTIN-3 (cont.)

Resources: (cont.)


FDA 510K Summary for BGM Galectin-3® System:

- FDA-approved indication: for use in conjunction with clinical evaluation as an aid in assessing the prognosis of individuals diagnosed with chronic heart failure (HF).