I. Policy: COVID19 Antibody Testing

II. Purpose/Objective:
   To provide a policy of coverage regarding COVID19 Antibody Testing

III. Responsibility:
   A. Medical Directors
   B. Medical Management

IV. Required Definitions
   1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
   2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
   3. Devised – the date the policy was implemented.
   4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
   5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;

b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;

c. in accordance with current standards of good medical treatment practiced by the general medical community.

d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
COVID19 antibody assays help determine whether someone has ever been infected with SARS-CoV-2 virus, even if they never had symptoms of infection. COVID19 antibody tests detect waning or past SARS-CoV-2 virus infection by measuring the individual’s immune response to the virus. At present, the immunologic correlates of immunity from SARS-CoV-2 infection are not well defined. Currently, the Centers for Disease Control and Prevention (CDC) recommendations state:

“Serologic test results should not be used to make decisions about grouping persons residing in or being admitted to congregate settings, such as schools, dormitories, or correctional facilities. Serologic test results should not be used to make decisions about returning persons to the workplace.”


FOR COMMERCIAL/MEDICARE BUSINESS SEGMENTS

INDICATIONS:
Currently, the Plan will consider the following indications for COVID19 antibody testing to be medically necessary only when ordered by a treating clinician:

- A member with symptoms consistent with COVID19 infection and multiple negative PCR tests to COVID 19; or
- A member who has recovered from a documented COVID19 infection and is now considering plasma donation; or
- A child with suspected Multisystem Inflammatory Syndrome in Children (MIS-C)

LIMITATIONS:
COVID19 antibody testing will be limited to one (1) test per year.

COVID19 antibody testing must be obtained through an in-network lab provider.

Occupational requirements for COVID19 antibody testing established by a member’s employer as a benchmark for returning to the workplace are not currently supported by the CDC. Any such required testing will be expected to be provided through the employer’s employee health program.

Any state or federally mandated coverage directives will supersede this policy.

EXCLUSIONS:
There is insufficient published peer reviewed medical literature to support the use of COVID19 antibody testing for any indication not listed in this policy. The use of COVID19 antibody testing to diagnose a current COVID 19 infection; to screen the general population; to determine eligibility to return to work; or as a determinant of immunity is considered experimental, investigational or unproven and NOT COVERED.

There is insufficient published peer reviewed medical literature to support the use of unsupervised “at home” collection devices for COVID19 antibody testing for any indication. The use of these devices is considered experimental, investigational or unproven and NOT COVERED.

There is insufficient published peer reviewed medical literature to support the use of rapid COVID19 antibody testing for any indication. The use of rapid antibody tests is considered experimental, investigational or unproven and NOT COVERED.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: COVID19 antibody assays
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage, nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

86328 Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (e.g., reagent
LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
CDC Interim Guidelines for COVID-19 Antibody Testing in Clinical and Public Health Settings

This policy will be revised as necessary and reviewed no less than annually.

Devised:  5/20
Revised:  
Reviewed:

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.