**Keywords**: Medical, Policy, Introduction, Active, Retired, Experimental or Investigational

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**I. ACTION**

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**II. POLICY DISCLAIMER**

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement.

Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

**III. POLICY**

This document presents the introduction to the Johns Hopkins HealthCare LLC (JHHC) Medical Policies and provides definitions to key terms.

Medical policies are based on the most current research available at the time of policy development, state whether a medical technology, procedure, drug or device is investigational, cosmetic or medically necessary. Each medical policy, including the coding section, delineates what specific criteria must be met to substantiate medical necessity of a technology, procedure or device and whether prior authorization is required. When prior authorization is required, it is the responsibility of the ordering, requesting or prescribing provider to obtain that authorization. The Johns Hopkins HealthCare LLC (JHHC) Provider Website (contains approved medical policies for Advantage MD, Employer Health Programs (EHP), Priority Partners Managed Care Organization (PPMCO) and Uniformed Services Family Health Plan (USFHP).
Every Active Policy will identify whether a medical technology, procedure or device is deemed in whole or in part to be Reconstructive or Medically Necessary, Cosmetic or Investigational. These terms are defined below. Technologies, procedures and devices considered Investigational or Cosmetic will not be covered, and policies for these technologies, procedures and devices will document what Technology Evaluation Criteria have not been met. Under certain circumstances, some benefits may be provided for participants enrolled in clinical trials or being treated as compassionate care. For specific details see Policy CMS 03.01 Clinical Trials and CMS 20.04 Expanded Access and Compassionate Care.

JHHC uses high quality scientific evidence to determine if health services are safe and effective. High quality evidence is peer reviewed and relies on robust research design such as Randomized Controlled Trials.

### IV. DEFINITIONS

**Active Policy** - Policies that are currently used for purpose of medical necessity determination. Tiers:

- **A.** Active with annual review (A1) - Scheduled for review every year to ensure that the policy reflects current medical research given the rapidly developing state of the evidence. Determination of this status is based on:
  1. Federal approval of service, device or supply within last two years, **OR**;
  2. Significant shift of evidence within the last two years
- **B.** Active with bi-annual review (A2) - Scheduled for review every two years to ensure that policy reflects current medical research. Determination of this status is based on:
  1. Failure to meet A1 criteria, **OR**;
  2. Evidence of continuing research within last three years
- **C.** Active with review every three years (A3) - Scheduled for review every three years for one or more of the following reasons:
  1. The document is primarily administrative in nature, **AND/OR**;
  2. It addresses operational issues only, **AND/OR**;
  3. It is mandated by statute or regulation, **AND/OR**;
  4. It is unlikely that further published literature would change the determination.

**Medical Necessity** - Services, devices or supplies that are (COMAR, 2018):

- **A.** Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition, **AND**;
- **B.** Consistent with current accepted standards of good medical practice, **AND**;
- **C.** The most cost-efficient service that can be provided without sacrificing effectiveness or access to care, **AND**;
- **D.** Not primarily for the convenience of the consumer, the consumer's family, or provider, **AND**;
- **E.** Meet all Technology Evaluation Criteria

**Cosmetic** - A surgery which can be expected to improve a patient's physical appearance, but does not restore or materially improve a body function (COMAR, 2018). Cosmetic procedures are not considered medically necessary.

**Reconstructive** - Operative procedures performed on structures of the body to improve or restore bodily function or normal appearance resulting from disease, trauma, certain congenital defects, or previous therapeutic intervention. Reconstructive surgical procedures are considered medically necessary.

**Experimental or Investigational** - Services, devices, or supplies in which any one of the following may apply:
A. Fail to meet any of the Technology Evaluation Criteria, defined below, OR;
B. Used for indication not approved by FDA, OR;
C. Are generally not accepted as standard therapy in the medical community where either, OR;
   1. Alternative therapy exists OR;
   2. The technology cannot be lawfully marketed without approval of the U.S. Food and Drug Administration and approval for marketing has not been given at the time the technology is furnished.

Retired - No longer used for medical necessity determinations. Policies are retired for any one or more of the following reasons:

A. The technology, service or procedure covered by the policy has become standard of care and no longer requires prior authorization if benefits apply, AND/OR;
B. The policy or policies have been combined with or subsumed by another policy, AND/OR;
C. Alternative medical necessity criteria have been chosen for the technology, service or procedure (e.g. InterQual®).

For purposes of appeals and claims adjudication, retired policies will be identified as such, but remain on the Medical Policy webpage for a period of six months only.

Technology Assessment - The systematic evaluation of the properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences (World Health Organization, 2018).

Technology Evaluation Criteria (TEC) - A service, device or supply must meet all following criteria:

A. The technology must have final approval from the appropriate government regulatory bodies when indicated (TRICARE, FDA, CMS, MDH), AND;
B. There must be sufficient scientific evidence-based studies as determined by the committee to permit conclusions concerning the effect of the technology on health outcomes, AND;
C. The technology must improve the member's net health outcome, AND;
D. The technology must be as beneficial as any established alternatives, AND;
E. The improvement must be attainable outside the investigational settings.

V. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

VI. REFERENCES

Code of Maryland Regulations, COMAR 10.09.02.01, Definition of Medical Necessity. Retrieved on 10/17/2018

Cross Reference

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CMS03.01 - Clinical Trials

National Committee for Quality Assurance (NCQA) UM 2: A

Maryland MCO System Performance Standards and Guidelines, 7.2 (Qlarant)

UM62 - Lack of Clinical Review Criteria

UM63 - Medical Policy Development

VII. APPROVALS

Historic Effective Dates: 09/07/12, 10/22/03, 10/22/04, 10/21/05, 05/30/06, 10/13/06, 03/03/08, 03/02/09, 06/04/10, 08/23/11, 03/07/14, 09/05/14, 11/07/14, 09/02/16