JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS01.00
		Effective Date	01/01/2024
		Approval Date	11/21/2023
	Subject **Medical Policy Introduction**	*Supersedes Date*	07/05/2023
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This document applies to the following Participating Organizations:

Advantage MD	EHP	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: introduction, medical, Medical, Policy, Introduction, Active, Retired, Experimental or Investigational, policy

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS01.00
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

A. This document presents the introduction to the Johns Hopkins Health Plans (JHHP) Medical Policies and provides definitions of key terms.

B. JHHP Medical Policies are internally developed coverage criteria based on the most current research available at the time of policy development.

C. The Medical Policy team conducts a search for sound current scientific and clinical evidence to determine if health services are safe, effective, and medically necessary, using resources including but not limited to:

1. Published scientific studies in peer-reviewed medical literature, including:
    a. Systematic reviews (e.g Cochrane reviews);
    b. Randomized controlled trials (RCTs);
    c. Cohort studies;
    d. Case-controlled studies;
    e. Case series.
2. Critically-appraised topics, including:

a. Published formal technology assessments (e.g. Hayes, Inc., AHRQ);
b. Published clinical guidelines of national professional medical associations (refer to CMS11.01 Clinical Practice Guidelines).

3. Critically-appraised article synopses;
4. Information from appropriate government regulatory bodies (e.g., Defense Health Agency [DHA], Center for Medicare & Medicaid Services [CMS], Maryland Department of Health [MDH], Food and Drug Administration [FDA]);
5. National medical policies;
6. Published reports by national expert organizations (e.g., USPSTF);
7. Evidence-based evaluations and clinical support resources (e.g. UpToDate);
8. A process for seeking input from subject-matter expert specialists and professionals with relevant expertise.

D. Each medical policy delineates specific criteria that must be met to substantiate the medical necessity of a technology, procedure or device.

E. Medical policies identify whether a medical technology, procedure or device is deemed in whole or in part to be medically necessary, cosmetic/reconstructive, or experimental & investigational. *Refer to the Definitions section.*

F. Unless specific benefits are provided under the member's contract, technologies, procedures and devices considered investigational or cosmetic will not be covered. Investigational services may be provided under certain circumstances, such as:

1. Participants enrolled in clinical trials, refer to: Medical Policy CMS03.01 Clinical Trials
2. Compassionate care, refer to: Medical Policy CMS20.05 Expanded Access and Compassionate Use

G. The criteria identified in Johns Hopkins Medical Polices are superseded by regulations and are available when coverage criteria are not fully established by statute or regulation for each JHHC Plan. Medical Policies are applied as follows:

1. *Advantage MD*: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
2. *Employer Health Programs (EHP)*: Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.
3. *Johns Hopkins Health Plan of Virginia, Inc. (JHHPVA)*: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
4. *Priority Partners (PPMCO)*: Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
5. *US Family Health Plan (USFHP)*: Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

H. JHHP Medical Policies used for Utilization Management (UM) decision-making include the following sections when applicable:

1. *Action*: Identifies the policy status - new, revised, superseded, retired;
2. *Policy Disclaimer:* Advises that each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy;
3. *Policy:* a section designed to direct the end-user to review links to Plan-specific regulations and resources prior to applying Medical Policy criteria;
4. *Policy Criteria*: Clinical review criteria to be used when coverage criteria are not fully established by Plan-specific regulations and resources;
5. *Definitions*: defines key terms;
6. *Background*: Includes a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;
7. *Coding Disclaimer*: Plan-specific statements describing the hierarchy of clinical criteria application prior to use of the JHHP Medical Policy;

8. *Coding Information*: A listing of CPT/HCPCS codes applicable to the policy scope;
9. *Reference Statement*: A statement on updating the list of references;
10. *References*: A list of sources used in the development of the Medical Policy.

I. The Medical Policy Advisory Committee (MPAC), which includes a majority of participating practitioners, representing various specialists including geriatrics, reviews and approves the medical policies. Subject-matter experts in the relevant clinical area are consulted to advise and comment on policy development and updates as needed. The majority of physician voting members are not affiliated with the JHHP.

J. JHHP Medical Polices are reviewed annually. Policies are revised, combined or retired as appropriate based on a review of current scientific evidence, regulatory requirements, and utilization of the services. Active policies are revised based on evolving evidence to keep pace with changes in medical and behavioral healthcare and to ensure members have access to safe and effective care. When new scientific evidence is not available, the Medical Policy Team, including JHHP Medical Director(s) determine if further review is required. The schedule for policy review considers the following conditions:
1. Rapidly developing state of the evidence;
2. Significant shift in scientific evidence;
3. Federal/State mandate by statute or regulation of a service, device or supply;
4. Regulatory requirement;
5. Internal decision.

K. Active JHHP Medical Policies for Advantage MD, Employer Health Programs (EHP), Johns Hopkins Health Plan of Virginia, Inc. (JHHPVA), Priority Partners Managed Care Organization (PPMCO), and Uniformed Services Family Health Plan (USFHP) are internally created and published in Hopkins Policies Online (HPO) and externally published on the The Johns Hopkins Health Plans (JHHP) Provider Website. JHHP Medical Polices are also available to providers/ members upon request.

L. Retired JHHP Policies will be removed from the Medical Policy Provider page and the Hopkins Policy Online (HPO) published manual, identified as such, and be accessible internally for the purposes of appeals, and claims adjudication and post-payment auditing.

M. When prior authorization is required, it is the responsibility of the ordering, requesting or prescribing provider to obtain that authorization.

IV. DEFINITIONS

Active Policy: Policies that are in current use for purpose of medical necessity determination.

Approvals: A list of all prior published dates, located in the Approvals section of each policy.

Cosmetic:

- COMAR 10.67.06.27 Benefits — Limitations: Cosmetic surgery when performed solely to maintain normal physical appearance or enhance beyond average level toward an aesthetic ideal.
- TRICARE Policy Manual 6010.63-M, April 2021, Chapter 4, Section 2.1 Cosmetic, Reconstructive, and Plastic Surgery – General Guidelines: Cosmetic, reconstructive, and/or plastic surgery is defined as surgery or treatments (including procedures, drugs, and devices) which can be expected primarily to improve the physical appearance of a beneficiary, and/or which is performed primarily for psychological purposes, and/or which restores form, but does not correct or materially improve a bodily function.
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16, Section 120 Cosmetic Surgery: Cosmetic surgery or expenses incurred in connection with such surgery is not covered. Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (i.e., as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. For example, this

exclusion does not apply to surgery in connection with treatment of severe burns or repair of the face following a serious automobile accident, or to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.

Coverage Criteria Not Fully Established: To ensure Medicare Advantage Plans provide the same access to care as those enrolled in traditional Medicare, CMS identifies when internal clinical coverage criteria may be used for medical necessity determination by defining when CMS criteria are not fully established, as follows:

- Additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. The MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;
- NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or
- There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria (42 CFR 422.101).

Experimental or Investigational**:** Services, devices, or supplies to which any one of the following may apply:

- Fail to meet Technology Evaluation Criteria, defined below, OR;
- Used for indication not approved by FDA, OR;
- Are generally not accepted as standard medical care in the medical community for the condition, disease, illness, or injury being treated where either,
  - An alternative therapy exists OR;
  - 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.

Medical Necessity:

- COMAR 10.67.01.01 – Definitions. "Medically necessary" means that the service or benefit is:
  - Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;
  - Consistent with current accepted standards of good medical practice;
  - The most cost efficient service that can be provided without sacrificing effectiveness or access to care; and
  - Not primarily for the convenience of the consumer, the consumer's family, or the provider.
- TRICARE Operations Manual 6010.63-M, April 2021. Medical Necessity Determination: A review to determine if the recommended health care services are reasonable for the diagnosis and treatment of illness, injury, pregnancy, mental disorders and adequate for well-baby care.
- CMS. Medically necessary: Services or supplies that are proper and needed for the diagnosis or treatment of your medical condition, are provided for the diagnosis, direct care, and treatment of your medical condition, meet the standards of good medical practice in the local area, and aren't mainly for the convenience of you or your doctor.

Policy Dates: Policy dates have the following meaning:

- Effective date: This date reflects the date the policy will be in use for medical necessity decision-making and aligns with the publication date.
- Approval date: This date reflects the date of the clinical review by the Medical Policy Advisory Committee and will align with the MPAC meeting date or final e-vote date, unless significant evidence or regulatory changes require a policy update off-cycle.

- Supersedes date: This date reflects the previous *Effective date* when the policy was last published, which the current version will replace.
- Original date: This is the date the policy was first published

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 may be considered medically necessary.

Retired Policy: Policy is no longer used for current medical necessity determinations. Policies are retired for anyone or more of the following reasons:

- The technology, service or procedure covered by the policy has become standard of care and no longer requires prior authorization if benefits apply, OR;
- The policy or policies have been combined with or subsumed by another policy, OR;
- Alternative medical necessity criteria have been chosen for the technology, service or procedure (e.g. InterQual®, delegation to external entity (e.g., eviCore)), OR;
- Low or no utilization of the technology, procedure, service, device, or supply, OR;
- Lack of business need for a Medical Policy (e.g., converted to a Reimbursement policy).

Superseding Policy: A policy that has replaced another policy. This may occur when policies are replaced or are combined and policy numbers are changed.

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 (NIH, 2017).

Technology Evaluation Criteria (TEC): A technology, procedure, service, device or supply must meet the 5 following TEC criteria:

1. The technology must have final approval from the appropriate government regulatory bodies when indicated (TRICARE, FDA, CMS, MDH), AND;
2. 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;
3. The technology must improve the member's net health outcome, AND;
4. The technology must be as beneficial as any established alternatives, AND;
5. The improvement must be attainable outside the investigational settings.

V. REFERENCE STATEMENT

Analyses of the references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published information and adjust the references below accordingly if deemed necessary.

VI. REFERENCES

Code of Federal Regulations (CFR) 42 CFR § 422.101 Requirements relating to basic benefits. https://www.ecfr.gov

Code of Federal Regulations (CFR) 42 CFR § 422.137 Medicare Advantage Utilization Management Committee. https://www.ecfr.gov

Code of Federal Regulations (CFR) 42 CFR § 438.236. Practice Guidelines.https://www.ecfr.gov

Code of Maryland Regulations (COMAR) 10.09.02.01 Definitions. https://dsd.maryland.gov/

Code of Maryland Regulations (COMAR) 10.67.01.01 Definitions. https://dsd.maryland.gov/

JHHC Medical Policy CMS03.01 Clinical Trials. https://hpo.johnshopkins.edu/

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JHHC UM Policy UM63 Medical Policy Development

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World Health Organization, (2020). Health Technology Assessment. www.who.int/teams/health-product-policy

VII. APPROVALS

Historic Effective Dates: 09/07/2012, 10/22/2003, 10/22/2004, 10/21/2005, 05/30/2006, 10/13/2006, 03/03/2008, 03/02/2009, 06/04/2010, 08/23/2011, 03/07/2014, 09/05/2014, 11/07/2014, 09/02/2016, 01/02/2019, 02/01/2021, 02/15/2022, 05/02/2022, 05/01/2023, 08/21/2023, 01/01/2024