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Clinical Policy Document: Implantable Prosthetic Devices Billed Under Miscellaneous HCPCS Codes	Date Approved: 09/09/26
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PLANS IN SCOPE

Aspirus Health Plan

BACKGROUND & PURPOSE:

Implantable prosthetic devices are used across multiple surgical specialties to replace, reconstruct, support, stabilize, or restore anatomical structures and physiological function. Emerging implant technologies may include patient-specific implants, additively manufactured (3D-printed) implants, advanced biomaterial implants, antimicrobial-coated implants, and other prosthetic technologies intended to improve implant performance, osseointegration, or durability

These devices may be utilized in orthopedic reconstruction, joint arthroplasty, revision arthroplasty, tumor reconstruction, and other medically necessary surgical procedures.

In certain circumstances, implantable prosthetic devices are billed using miscellaneous HCPCS codes when no existing HCPCS code adequately identifies the implanted technology. Examples include HCPCS L8699 (Prosthetic implant, not otherwise classified). Miscellaneous HCPCS codes describe a billing mechanism rather than a distinct clinical technology and therefore do not independently establish medical necessity. Coverage determinations require evaluation of the underlying diagnosis, surgical procedure, implanted device, clinical rationale, and supporting documentation.

The purpose of this policy is to:

- Establish a framework for evaluating implantable prosthetic devices billed under miscellaneous HCPCS codes;
- Define when such devices may be considered medically necessary;
- Promote consistent evidence-informed utilization review;
- Clarify documentation requirements;
- Clarify that coding alone does not determine coverage.

This policy does not endorse specific devices, implant manufacturers, proprietary technologies, implant designs, or surgical approaches. Procedure-specific medical necessity determinations remain subject to applicable utilization management criteria, clinical guidelines, and related medical policies.

COVERAGE INDICATIONS:

Medically Necessary Use

Implantable prosthetic devices billed under miscellaneous HCPCS codes may be considered medically necessary when ALL of the following criteria are met:

1. Underlying Procedure: The underlying surgical procedure is medically necessary under applicable:
 - Medical policies;
 - InterQual criteria;
 - MCG criteria;
 - Evidence-based utilization management standards; or
 - Other applicable clinical review frameworks.
2. Device Necessity: The implanted prosthetic device is integral to the covered procedure and is intended to:
 - Replace absent anatomy;
 - Restore anatomical structure;
 - Restore joint function;
 - Restore biomechanical stability;
 - Restore physiological function;
 - Facilitate medically necessary reconstruction; or
 - Treat disease, injury, trauma, congenital abnormality, or surgical defect.

3. Regulatory Status: The device is:

- FDA-cleared;
- FDA-approved;
- Authorized through another applicable FDA pathway; or
- Otherwise legally marketed for the intended use.

4. Clinical Documentation: Documentation supports the clinical necessity of the implanted device and sufficiently identifies the device being implanted.

Device Specific Review

Clinical review may consider:

- FDA labeling and indications for use;
- Peer-reviewed literature;
- Specialty society recommendations;
- Accepted standards of medical practice;
- Clinical rationale supporting device selection;
- Applicable coverage guidance and utilization management criteria.

Examples of implantable prosthetic devices potentially reviewed under this policy include:

- Joint replacement prostheses;
- Revision arthroplasty prostheses;
- Tumor reconstruction prostheses;
- Structural reconstructive implants;
- Patient-specific reconstructive implants;
- Additively manufactured (3D-printed) prosthetic implants;
- Advanced biomaterial reconstructive implants;
- Antimicrobial-coated implantable prosthetic devices;
- Other surgically implanted prosthetic devices reported under miscellaneous coding mechanisms.

Coverage is determined by the underlying clinical indication and procedure rather than by the miscellaneous HCPCS code.

Experimental/ Investigational Use

Implantable prosthetic devices billed under miscellaneous HCPCS codes are considered experimental, investigational, or unproven when any of the following apply:

- The device lacks appropriate regulatory authorization for the intended use;
- Available evidence is insufficient to establish safety or effectiveness;
- The intended use falls outside accepted standards of medical practice;
- The underlying procedure has not been established as medically necessary;
- Clinical documentation is insufficient to support the requested use.

Services determined to be experimental, investigational, or unproven are not covered.

Exclusions

The following are not covered:

- Insufficient documentation to identify the implanted device;
- Non-covered underlying surgical procedures;
- Device use based solely upon provider preference;
- Device use based solely upon manufacturer preference;

- Device use based solely upon convenience;
- Device use based solely upon marketing claims;
- Experimental, investigational, or unproven indications;
- Clinical scenarios in which evidence does not support the requested use.

LIMITATIONS

Coverage is subject to the following:

- Use of a miscellaneous HCPCS code does not establish coverage.
- Use of HCPCS L8699 does not independently establish medical necessity.
- Coverage determinations are based upon:
 - The underlying diagnosis;
 - Medical necessity of the procedure;
 - Intended clinical purpose of the implanted device;
 - Supporting documentation.
- This policy does not establish procedure-specific medical necessity criteria.
- Procedure-specific criteria may be addressed through:
 - InterQual;
 - MCG;
 - Specialty-specific medical policies;
 - Other delegated utilization management tools.

Selection of implant type, design, manufacturer, and surgical approach remains the responsibility of the treating provider.

MEDICAL RECORDS DOCUMENTATION

Benefit coverage is determined according to member-specific plan documents and applicable state and federal requirements.

Documentation must support all coverage criteria and may include:

- Underlying diagnosis;
- Surgical indication;
- Operative plan;
- Manufacturer name;
- Product name;
- Device description;
- Implant technology characteristics, when applicable;
- Documentation describing customized or patient-specific implant design, when applicable;
- FDA status, when applicable;
- Clinical rationale for device selection;
- Supporting rationale for selection of a novel implant technology when clinically relevant;
- Supporting imaging, pathology, or procedure documentation when clinically relevant.

Submission of medical records does not guarantee coverage.

DEFINITIONS

Implantable Prosthetic Device:

A surgically implanted device used to replace, reconstruct, restore, support, or stabilize anatomical structures or physiological function.

Miscellaneous HCPCS Code:

A HCPCS billing code used when no more specific HCPCS code adequately describes the reported device, technology, or service.

HCPCS L8699:

Prosthetic implant, not otherwise classified.

Medical Necessity:

Health care services or supplies required to diagnose or treat illness, injury, disease, condition, or symptoms and that meet accepted standards of medical practice.

APPLICABLE CODES

Note: Codes are provided for reference only. Coverage is determined by clinical criteria above.

HCPCS Codes

- L8699- Prosthetic implant, not otherwise classified

POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
09/09/2026	Initial Policy Development	Optum Medical and Pharmacy Subcommittee

REFERENCES:

Guidelines & Consensus Statements

American Academy of Orthopaedic Surgeons (AAOS). (2022). Clinical Practice Guideline: Surgical Management of Osteoarthritis of the Knee. www.aaos.org. Accessed 08/10/26.

Centers for Medicare & Medicaid Services (CMS). (2020). Total Knee Arthroplasty: Medical Necessity and Documentation Requirements. www.cms.gov. Accessed 08/10/26.

National Institute for Health and Care Excellence (NICE). (2020). Joint Replacement (Primary): Hip, Knee and Shoulder (NG157). Reviewed 2024. www.nice.org.uk. Accessed 08/10/26.

Clinical Evidence (Trials, Registries, Systematic Reviews)

Alhifzi, Z. (2024). Systematic review and meta-analysis of long-term outcomes and innovations in total knee arthroplasty: Kinematic, personalized knee versus conventional. *Orthopedic Reviews*, 16. <https://doi.org/10.52965/001c.122318>

Cacciola, G., Giustra, F., Bosco, F., Sabatini, L., Risitano, S., De Meo, F., Braconi, L., Cavaliere, P., Massè, A., & Solarino, G. (2023). Long-term follow-up of medial pivot total knee arthroplasty: A systematic review of the current evidence. *Prosthesis*, 5(3), 622-634. <https://doi.org/10.3390/prosthesis5030044>

Evans, J. T., Walker, R. W., Blom, A. W., Whitehouse, M. R., Timperley, A. J., & Sayers, A. (2019). How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. *The Lancet*, 393(10172), 655-663. [https://doi.org/10.1016/S0140-6736\(18\)32531-5](https://doi.org/10.1016/S0140-6736(18)32531-5)

Review Articles

Misir A. (2025). Current developments in orthopaedic implant technology. *Journal of orthopaedic surgery and research*, 20(1), 927. <https://doi.org/10.1186/s13018-025-06279-w>

Coding and Regulatory References

Centers for Medicare & Medicaid Services. (2026). *Healthcare Common Procedure Coding System (HCPCS) Level II*. U.S. Department of Health and Human Services.

Centers for Medicare & Medicaid Services. (2026). *HCPCS code L8699: Prosthetic implant, not otherwise classified*. U.S. Department of Health and Human Services.

Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).