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Medicare Coverage of Gender-Affirming Surgery

Issue Brief for Trans Maryland
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General Coverage Policies

Medicare covers "reasonable and necessary" medical care for its beneficiaries,[1] including the following services for transgender and gender diverse individuals: [2]

- Medically necessary transition-related surgery
- Medically necessary hormone therapy (covered under Part D prescription drug benefit)
- Routine preventive care, regardless of gender marker (there is a specific billing code that can be applied to the claim to bypass being rejected for a "gender/procedure conflict".)[3]

In general, Medicare covers services which:

- Fall within a general Medicare benefit category defined in Title XVIII of the Social Security Act (the Act), Section 1861[4] (e.g., physician services)
- Do not fall within one of the statutorily excluded categories listed in Section 1862[5] (e.g., cosmetic surgery, experimental procedures)
- Are considered "reasonable and necessary" as described in Section 1862(a)(1)(A).[6] This determination applies if the service is:
    - Safe and effective;
    - Not experimental or investigational; and
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition, in a manner which meets, but does not exceed, the beneficiary's medical need.[7]

The specific circumstances for coverage of various services can be documented in a variety of ways, described below. However, it is important to note that the "reasonable and necessary" guidelines apply even if a service is not specifically documented through policies and guidelines. **For most medical care, medical necessity is determined on a case-by-case basis.**

Medical necessity for transition-related surgery (and therefore, eligibility for Medicare reimbursement) is determined on a case-by-case basis. For beneficiaries enrolled in Medicare fee-for-service (FFS) (Parts A&B, aka "Original Medicare"), the determination is made by a regional Medicare Administrative Contractor (MAC); for beneficiaries enrolled in Medicare

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[1] https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00099545
[2] https://transequality.org/know-your-rights/medicare
[3] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1877CP.pdf
[4] https://www.ssa.gov/OP_Home/ssact/title18/1861.htm
[5] https://www.ssa.gov/OP_Home/ssact/title18/1862.htm
[6] Title XVIII of the Social Security Act, Section 1862(a)(1)(A) allows coverage and payment for items and services that are "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."
[7] https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00099545

Advantage (Part C), determination is made by the health insurance plan selected by the beneficiary. In both cases, MACs and Medicare Advantage (MA) plans develop their own policies and procedures for evaluating medical necessity,[8] consistent with statutory and national coverage policy.

In practice, what this means is that Medicare should cover medically necessary transition-related care (regardless of whether the beneficiary is enrolled in Original Medicare or Medicare Advantage), and that medical necessity will need to be established for each specific case, following documentation requirements or guidelines set by the MAC or MA plan. **However, there may be variation across MACs and MA plans in the interpretation of what precisely is medically necessary – the specific procedures covered, as well as clinical criteria and documentation required for a case to qualify for reimbursement.**

Medicare Exclusion on Cosmetic Procedures

There are a number of gender-affirming procedures (e.g., breast augmentation, liposuction) that are considered cosmetic when performed as elective procedures, i.e. not for the treatment of gender dysphoria. The Medicare program has a statutory exclusion for cosmetic procedures; Title XVIII of Social Security Act, Section 1862(a)(10) specifically excludes cosmetic surgery, except as required for the prompt repair of accidental injury or for the improvement of the functioning of a malformed body member; this exclusion is noted in the Medicare Benefit Policy Manual, Chapter 16.[9]

However, according to the WPATH Standards of Care, these procedures are not considered cosmetic when performed as a medically necessary treatment for gender dysphoria:

> "Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient… Consequently, WPATH urges health care systems to provide these medically necessary treatments and eliminate any exclusions from their policy documents and medical guidelines that preclude coverage for any medically necessary procedures or treatments for the health and well-being of transgender and gender diverse individuals."[10]

While the WPATH Standards of Care do not represent binding Medicare coverage policy, the Medicare Appeals Council, the highest level of administrative review of Medicare coverage policy, has previously ruled that "in the absence of an NCD, LCD, or any other CMS policy, the Council finds that the WPATH Standards of Care[11] are reasonable guidelines to determine

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[8] For example, one MAC (Noridian) policy indicates, "All coverage determinations for transgender surgery are currently handled by individual consideration on a case by case review with particular consideration of the World Professional Association for Transgender Health (WPATH) Standards of Care as interpreted through the various Medicare statutes, rules, regulations, and Manual instructions."

[9] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf

[10] Chapter 2, Statement 2.1: https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

[11] https://www.wpath.org/publications/soc

medical necessity."[12] The WPATH Standards of Care clearly define these procedures as medically necessary for the treatment of gender dysphoria, and provide specific clinical criteria for assessment and indication of treatment. **By this logic, the Medicare coverage exclusion for cosmetic procedures should not apply to medically necessary treatment for gender dysphoria which meets the WPATH Standards of Care.**

However, it is likely that there is inconsistency in how this is interpreted by MACs and MA plans, particularly for initial claims determinations, due to the lack of clear national billing guidance. Claims might be denied based on procedure codes alone, without adequate review for medical necessity. The appeals process would allow providers and beneficiaries an opportunity to challenge the denial and demonstrate medical necessity.

History of Medicare Coverage for Gender-Affirming Surgery

Prior to 2014, Medicare did not cover transition-related surgery due to a longstanding policy categorizing such procedures as "experimental". That exclusion was eliminated in 2014, meaning that Medicare could begin to cover medically necessary transition-related surgery, consistent with the "reasonable and necessary" guidelines considering the individual's specific circumstances.

In December 2015, a formal request was submitted to CMS to consider making a National Coverage Determination on gender reassignment surgery for Medicare beneficiaries with gender dysphoria.[13]

Most Medicare coverage is not subject to NCDs. The NCD process is typically only used in the following situations:

- Local coverage policies across the regional MACs are inconsistent.
- The service represents a significant medical advance, and no similar service is currently covered by Medicare.
- The service is the subject of substantial controversy.
- The potential for rapid diffusion or overuse exists.[14]

CMS does not make many NCDs because:

- Most decisions about what services should be covered are not controversial.
- There are limited CMS resources to initiate NCDs and ensure they remain current with the standard of care.
- Providers are often apprehensive to request a NCD because the decision could result in coverage limitations or non-coverage if evidence is thin. Without an NCD, providers can submit for reimbursement and make the case for clinical benefit on a case-by-case basis.

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[12] https://www.hhs.gov/sites/default/files/static/dab/decisions/council-decisions/m-15-1069.pdf

[13] https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id282.pdf

[14] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar03_AppB.pdf

> This affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule.

In 2016, in response to the formal request received in 2015, CMS performed a National Coverage Analysis (NCA) to determine whether a NCD was warranted for transition-related surgery. To issue a NCD, CMS must have adequate evidence that the service improves outcomes in the Medicare population. **In 2016, after a review of the evidence, CMS determined there was insufficient clinical evidence for the Medicare population to support a coverage decision for transition-related surgery.**[15] Specifically, CMS cited limited data on specific health outcomes and the characteristics of patient populations that might benefit from transition-related surgery, i.e. the patient population for which the services would be reasonable and necessary. The decision was documented via a program memorandum MM9981[16] as well as a note in the Medicare NCD manual and instructions issued to MACs.[17]

CMS was careful to note that this was not a decision of national non-coverage for transition-related surgery, simply that there was insufficient evidence to meet the requirements for a NCD for the Medicare population. CMS reiterated that MACs would continue to make case-by-case determinations of coverage after considering the individual beneficiary's circumstances.

In response to comments questioning whether bias might play into MAC coverage decisions, CMS noted "With respect to the concern about potential bias by Medicare contractors, we have no reason to expect that the judgments made on specific claims will be influenced by an overriding bias, hostility to patients with gender dysphoria, or discrimination. Moreover, the Medicare statute and our regulations provide a mechanism to appeal an adverse initial decision if a claim is denied and those rights may include the opportunity for judicial review. We believe the Medicare appeals process would provide an opportunity to correct any adverse decision that was perceived to have been influenced by bias."[18] Coverage denials have been successfully challenged through appeals,[19] though the process can be lengthy.

Specific Coverage Policies

In general, CMS documents the specific circumstances for coverage of various services in any of the following ways:

- National Coverage Determinations (NCDs)
- Other CMS guidelines, such as program manuals, billing guidance, and memoranda (which are binding, but do not go through the same process as a NCD)

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[15] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=282

[16] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm9981.pdf

[17] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R194NCD.pdf

[18] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=282

[19] https://www.hhs.gov/sites/default/files/static/dab/decisions/council-decisions/m-15-1069.pdf

- Local Coverage Determinations (LCDs) made by a MAC[20]
- Other guidelines developed by a MAC

There is no NCD for transition-related surgery. One MAC (Palmetto GBA, regions J & M) has an LCD for gender reassignment surgery, which is effective in AL, GA, TN, NC, SC, WV, and VA (excluding DC metro for Part B services).[21] This provides clear guidance on which procedure (CPT) codes are covered or not covered as well as the clinical circumstances, documentation, and diagnosis codes (ICD) required to establish medical necessity. Novitas Solutions, the MAC for region H (MD, DE, PA, NJ, DC, and part of VA), has no LCD for gender reassignment surgery.

In the absence of an NCD or LCD (so, in all other states), medical necessity is determined on a case-by-case basis, which is how Medicare handles coverage for most medical care. However, there is also very little guidance provided by way of the CMS program manuals, claims/billing guidance, or other memoranda. As a result, there may variation between or even within MACs in how medical necessity is determined for beneficiaries enrolled in Original Medicare. In Medicare Advantage, some plans reference their standard commercial policy as a guideline.[22]

Further, it may be difficult for providers or beneficiaries to verify coverage for a specific case in advance of the procedure. Due to resource limitations, many MACs are unable to perform coverage predeterminations (which are common for commercial insurers). This means that the **provider or beneficiary may not be able to verify coverage until the procedure has been completed and the claim submitted, putting them at financial risk if the claim is denied**.

The Medicare Appeals Council, the highest level of administrative oversight of Medicare coverage, noted in a 2016 decision that "in the absence of an NCD, LCD, or any other CMS policy, the Council finds that the WPATH Standards of Care[23] are reasonable guidelines to determine medical necessity."[24] This precedent suggests that denied claims following those standards would eventually be righted during the appeals process. While the WPATH standards do not represent binding guidance to the MACs or MA plans, citing those standards and coverage precedent in claims documentation will likely strengthen the rationale for medical necessity of Medicare coverage.

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[20] According to the Medicare Program Integrity Manual, LCDs can be issued when there is a validated widespread problem involving high dollar or high volume services; an LCD is necessary to assure beneficiary access to care; or frequent denials are issued or anticipated as a result of postpayment claims review. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033

[21] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53793&ver=25&bc=CAAAAAAAAAAA

[22] https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-coverage-sum/cosmetic-reconstructive-procedures.pdf

[23] https://www.wpath.org/publications/soc

[24] https://www.hhs.gov/sites/default/files/static/dab/decisions/council-decisions/m-15-1069.pdf

Appeals

There is a robust appeals process to give providers and beneficiaries recourse to demonstrate medical necessity if a claim is initially denied, but the process can be lengthy.[25] If an appeal is dismissed at the first level of the process, the claim can be appealed up to the second level, and so on.

1. **Level 1: Redetermination by the MAC**. The review is made by personnel at the MAC not involved in the initial claim determination.[26]
2. **Level 2: Reconsideration by a QIC**. This review is done by a different CMS claims review contractor, known as a Qualified Independent Contractor (QIC).[27]
3. **Level 3: Administrative Law Judge hearing**. ALJs work in the Office of Medicare Hearings and Appeals (OMHA), which sits within HHS but is independent of CMS. This provides a fair and impartial forum to address disagreements with CMS Medicare coverage and payment determinations.[28] If the ALJ does not render a decision within 90 days (a common issue in recent years due to a backlog of appeals), the appellant may request the appeal escalate to the next level.[29]
4. **Level 4: Medicare Appeals Council Review**. The Council's Administrative Appeals Judges sit within the HHS Departmental Appeals Board (DAB), which is independent of both CMS and OMHA. This is the final level of administrative appeals for Medicare claims.[30]
5. **Level 5: Judicial Review in U.S. District Court**. Once administrative appeals are exhausted, an appellant can request judicial review in Federal district court.

In Original Medicare, if a MAC initially denies a claim, and this denial is reversed in the appeals process, the claim will be paid and the case closed. However, in the Medicare Advantage program, insurers also have certain rights of appeal. This means that if a Medicare Advantage plan initially denies a claim, but the denial is reversed in the appeals process, the insurer could then appeal that decision and request the initial denial be upheld.

So what is a provider in Maryland to do?

In the absence of specific coverage parameters, providers and beneficiaries might look to existing standards and precedent for Medicare coverage as a reasonable starting point for demonstrating medical necessity to their local MAC or MA plan.[31] Some options include:

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[25] https://www.cms.gov/medicare/appeals-and-grievances/orgmedffsappeals/downloads/flowchart-ffs-appeals-process.pdf

[26] https://www.cms.gov/medicare/appeals-and-grievances/orgmedffsappeals/redeterminationbyamedicarecontractor

[27] https://www.cms.gov/medicare/appeals-and-grievances/orgmedffsappeals/reconsiderationbyaqualifiedindependentcontractor

[28] https://www.cms.gov/medicare/appeals-and-grievances/orgmedffsappeals/omha-alj-hearing

[29] https://www.hhs.gov/sites/default/files/omha/files/medicare-appeals-backlog.pdf

[30] https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/05AppealsCouncil

[31] Beneficiaries enrolled in Medicare Advantage might also look to that issuer's commercial coverage policy as a standard to reference, even if it does not explicitly apply to the Medicare Advantage plan.

- **The Palmetto GBA LCD**.[32] Also technically only binding in some states,[33] it represents a clear standard for Medicare coverage that has met federal requirements for review and could be used as a reference point elsewhere.
    - **Advantages**: Very specific list of covered procedures (genital and breast) and clear documentation requirements.
    - **Disadvantages**: Excludes procedures historically considered "cosmetic", which is not consistent with the current WPATH standards of care.
- **The WPATH Standards of Care**.[34] The Medicare Appeals Council set the precedent in 2016 that the WPATH SOC is a reasonable guideline for determining medical necessity for Medicare coverage in the absence of a NCD or LCD.[35]
    - **Advantages**: Represents the current standard of care that has been documented and thoroughly vetted in the medical community; includes evidence of medical necessity for a wide variety of procedures, including those historically considered cosmetic or experimental.
    - **Disadvantages**: Less clear what specific documentation would support the demonstration of medical necessity for a Medicare beneficiary. Evidence may not be specific enough to demonstrate necessity in the Medicare population.

However, none of those guarantee that Novitas would use the same criteria for a given case. Providers may be able to get unofficial guidance from Novitas by requesting billing and documentation requirements. Even absent a LCD, there may be internal billing and documentation procedures that could shed light on what is likely to be initially approved or denied. Providers may also request predetermination of coverage from Novitas, though resource constraints may prevent an official decision.

What if that doesn't work?

What is covered in theory is not always covered in practice. A working group of providers might come together to share information about successful billing practices, to identify common challenges and specific asks for the MAC to clarify, and to determine if there are inconsistencies in coverage even within the MAC.

By creating a clearer picture of where the process is breaking down, as well as where it is working, providers will be better positioned to engage the MAC, or potentially CMS, in constructive dialogue. The Medicare program should in theory cover transition-related surgery under reasonable and necessary circumstances. If that theory is not translating to practice, the providers, CMS, and the MAC have a shared interest in finding solutions. It is not in the MAC or CMS interests to be found to be out of compliance with statute or at risk of discrimination claims.

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[32] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53793&ver=25&bc=CAAAAAAAAAAA

[33] AL, GA, TN, NC, SC, WV, and part of VA

[34] https://www.wpath.org/publications/soc

[35] https://www.hhs.gov/sites/default/files/static/dab/decisions/council-decisions/m-15-1069.pdf

As noted above, NCDs are not common, and CMS decided against issuing a NCD for transition-related surgery just 7 years ago. However, that decision was made shortly after Medicare lifted the exclusion on transition-related surgery, when there would have been little Medicare claims data to support the analysis. There is also a renewed focus at CMS on equity and reducing disparities, including specific actions underway to identify and address disparities for LGBTQIA+ beneficiaries.

A new NCD request might be warranted if:

- Since 2015, there has been additional published evidence of clinical benefit in the Medicare population (including those qualifying due to age as well as those under 65 qualifying due to disability.)
- There is evidence that coverage of these procedures is being interpreted in a substantially different manner across regions.
- There is evidence that coverage of these procedures is being interpreted in a substantially different manner than the generally accepted standard of care.

Even without a NCD or LCD, the Medicare program and MACs have a variety of mechanisms for clarifying billing and documentation requirements for procedures which can be used to address the second and third points above, particularly if there is evidence of a pattern in initial denials that are later approved through appeals. For example, if there were evidence that claims are being denied based on procedure code alone (e.g., procedures considered cosmetic when not for treatment of gender dysphoria), issuing a billing code that can help MACs to identify those claims separately from cosmetic procedures could help to reduce initial denials and increase provider confidence that the claim would be paid timely.