

## Perinatology

### 1. MCG Criteria Used

#### Clinical Criteria: MCG Care Guidelines, 30th Edition

- Amniocentesis (MCG ORG: A-0160 AC, 30th Edition)
- Pregnant Uterus Fetal Biophysical Profile with or without Nonstress Testing (MCG ORG: A-0435 AC, 30th Edition)

#### Applicable CPT / HCPCS Codes:

| CPT / HCPCS Code | Description                                                                                    |
|------------------|------------------------------------------------------------------------------------------------|
| 59000            | Amniocentesis, diagnostic                                                                      |
| 59001            | Amniocentesis, therapeutic amniotic fluid reduction, including ultrasound guidance             |
| 76946            | Ultrasonic guidance for amniocentesis, imaging supervision and interpretation                  |
| 76801-76817      | Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation |
| 76818, 76819     | Fetal biophysical profile, with and without nonstress testing                                  |
| 59025            | Fetal nonstress test                                                                           |

### 2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding perinatology services, including diagnostic amniocentesis and the fetal biophysical profile with or without nonstress testing, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of perinatology services and to determine when such services are medically necessary. Perinatal diagnostic testing balances the value of detecting fetal compromise or genetic and infectious conditions against the procedural risk to the pregnancy. Amniocentesis is invasive and carries a defined risk of pregnancy loss, while antepartum surveillance can either prevent stillbirth when appropriately applied or precipitate unnecessary intervention when overused. Absent consistent, evidence-based selection criteria, there is material risk of both inappropriate denial of medically necessary testing and inappropriate approval of testing that exposes the pregnancy to avoidable risk.

#### Potential Clinical Harms:

**Amniocentesis:** Inappropriate denial of amniocentesis in a pregnancy with a clear indication, such as a positive aneuploidy screen, suspected fetal infection, or the need to document fetal pulmonary maturity, could leave a diagnosable and potentially manageable condition undetected, removing the opportunity for informed decision-making and timely care. Conversely, inappropriate approval of amniocentesis without an indication exposes the pregnancy to a procedure-

attributable fetal loss rate of approximately 0.3 percent and additional risk in multiple gestations, without offsetting benefit.

**Fetal Biophysical Profile:** Inappropriate denial of the fetal biophysical profile in a pregnancy with risk factors for uteroplacental insufficiency could fail to detect fetal compromise, increasing the risk of stillbirth. Inappropriate approval in low-risk pregnancies generates equivocal results that prompt unnecessary obstetric intervention, including avoidable induction or cesarean delivery.

#### **Clinical Benefits:**

**Amniocentesis:** MCG criteria specify validated indications for amniocentesis drawn from obstetric specialty society guidance, including positive or high-risk aneuploidy screening, abnormal ultrasound findings, suspected fetal infection, and assessment of fetal pulmonary maturity. By tying the procedure to a defined indication, these criteria directly mitigate the harm of leaving a diagnosable condition undetected while protecting pregnancies without an indication from the procedure-attributable loss risk identified above.

**Fetal Biophysical Profile:** MCG criteria reserve the fetal biophysical profile for pregnancies with defined risk factors for fetal compromise and apply the validated scoring framework in which a score of 8 to 10 is normal, 6 is equivocal, and 4 or less is abnormal. This evidence-based selection directly counters the harm of undetected fetal compromise in at-risk pregnancies while preventing the unnecessary obstetric intervention that follows from testing low-risk pregnancies. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services, because the criteria incorporate appropriateness thresholds drawn from current obstetric specialty society guidelines and are unlikely to lead to inappropriate denials.

### **3. Explanation of Supplementation**

**Basis for Use:** Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for perinatology services. While Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical indications (e.g., which screening results or pregnancy risk factors warrant invasive diagnostic amniocentesis or antepartum fetal surveillance) required to distinguish indicated from nonindicated perinatal testing.

**Applicable Medicare References:** Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard Code of Federal Regulations: 42 CFR 410.32 (diagnostic tests; ordering and medical necessity) Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02) Medicare Program Integrity Manual, Chapter 6, Section 6.5 (CMS IOM Publication 100-08) Code of Federal Regulations: 42 CFR 419.22; 42 CFR 422.101 Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx> For these perinatology services, no specific NCD or LCD fully establishes clinical indication thresholds; Original Medicare criteria are not fully established, requiring supplementation. Within the above statutes and regulations, MCG criteria assist in determining the appropriateness of diagnostic amniocentesis based on defined indications and the appropriateness of fetal biophysical profile testing based on defined pregnancy risk factors and the validated scoring framework. Use of these criteria helps ensure perinatology services are not incorrectly denied when medically appropriate, nor incorrectly approved when not reasonable and necessary, and may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

## 4. Summary of Clinical Evidence

\*Note: The following evidence summary is derived directly from MCG Care Guidelines, 30th Edition (guidelines A-0160 and A-0435). The reference lists below are drawn from those respective MCG guidelines.\*

### Background

**Amniocentesis (MCG ORG: A-0160 AC)** Amniocentesis, the removal of amniotic fluid under ultrasound guidance, is generally performed during the second trimester (over 15 weeks gestation) for cytogenetic analysis of fetal cells; third-trimester amniocentesis is typically performed for nongenetic reasons such as documentation of fetal pulmonary maturity or exclusion of infection. A society guideline based on a systematic review states that the fetal loss rate attributable to amniocentesis is approximately 0.3 percent, and the risk is higher in twin pregnancies. First-trimester amniocentesis carries an increased risk of amniotic fluid leak, fetal loss, and talipes equinovarus and is not recommended.

**Fetal Biophysical Profile (MCG ORG: A-0435 AC)** The fetal biophysical profile is a noninvasive test used to gauge the presence or absence of fetal asphyxia and the risk of fetal death in the antenatal period. It uses ultrasound to score fetal breathing movement, fetal body movement, fetal tone, fetal heart rate reactivity (nonstress testing), and amniotic fluid volume, each scored 0 or 2 for a maximum of 10; a score of 8 to 10 is normal, 6 is equivocal, and 4 or less is abnormal. It is indicated in pregnancies with risk factors for uteroplacental insufficiency or fetal compromise.

### Evidence Summary

**Amniocentesis (MCG ORG: A-0160 AC)** This guideline (30th Edition) is supported by peer-reviewed articles and obstetric specialty society guidance establishing the indications for diagnostic amniocentesis, the procedure-attributable loss rate, and the elevated risk in multiple gestations and first-trimester procedures, supporting indication-based selection.

**Fetal Biophysical Profile (MCG ORG: A-0435 AC)** This guideline (30th Edition) is supported by peer-reviewed articles and obstetric consensus guidelines establishing the biophysical profile as a validated tool for antepartum fetal surveillance in at-risk pregnancies, with scoring thresholds that guide the need for further evaluation or delivery.

**Rationale (from MCG)** Use of these MCG care guidelines helps the clinician identify patient-specific clinical factors that establish the medical necessity of perinatal diagnostic testing. The evidence-based clinical criteria ensure patients receive the most appropriate evaluation for their specific clinical situation, reduce unnecessary procedural risk to the pregnancy, and provide a standard that can reduce disparities in care. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable NCDs or LCDs.

**Related CMS Coverage Guidance (as cited in MCG 30th Edition):** Code of Federal Regulations (CFR): 42 CFR 410.32; 42 CFR 419.22; 42 CFR 422.101; CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15; CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5; Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx>

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## 5. Public Accessibility

**Transparency Tool URL:** <https://akido.access.mcg.com/index>

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**Navigation Instructions:** To access these coverage summaries, navigate to the UM Criteria page, scroll to the bottom of the page, and click the Medical Necessity Supplementation Criteria link. All summaries are organized alphabetically by category.