

---

# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

---

Ruling No. 85-1

Date: 1982

---

HCFAR 85-1-1

MEDICARE PROGRAM

Hospital Insurance Benefits (Part A)

## Exclusion of Cytotoxic Leukocyte Testing from Medicare Coverage

HCFAR 85-1

**Purpose:** This Ruling announces HCFA's decision to exclude Medicare coverage of cytotoxic leukocyte testing for food allergies.

**Citations:** Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)); 42 CFR 401.108; 42 CFR 405.310(k); 50 FR 27691, July 5, 1985.

**Pertinent History:** We published a notice in the Federal Register on August 19, 1983 (48 FR 37716) proposing to exclude certain food allergy testing and treatment procedures from Medicare coverage. We received more than 19,000 comments on the notice; approximately 170 specifically mentioned cytotoxic leukocyte testing. These commenters oppose the elimination of Medicare coverage for this procedure. Their opposition is testimonial in nature and included no scientific studies supporting the efficacy of cytotoxic leukocyte testing for food allergies. Further, the Food and Drug Administration (on page 2 of its Compliance Policy Guide 7124.27 dated 3/19/85) states that the consensus of scientific opinion is that the cytotoxic test is unreliable as a diagnostic tool and is not generally recognized by qualified experts as effective. Therefore, based on all information available to us, we have determined that cytotoxic leukocyte testing lacks an acceptable scientific rationale, specificity, sensitivity, and evidence of clinical effectiveness.

---

HCFAR 85-1-2

**Ruling:** Cytotoxic leukocyte testing for food allergies is excluded from Medicare coverage because available evidence does not show that these tests are safe and effective.

**Effective Date:** August 5, 1985.

**Cross-References:** Identical instructions can be found in the following HCFA publications: Part A Intermediary Manual (HCFA Pub. 13-3), Chapter II, Coverage Issues Appendix, section 50-2; Medicare Carriers Manual (HCFA Pub. 14-3), Chapter II, Coverage Issues Appendix, section 50-2; Hospital Manual (HCFA Pub. 10), Coverage Issues Appendix, section 50-2.<sup>1</sup>

---

<sup>1</sup> These instructions were replaced by the Coverage Issues Manual after this Ruling's publication in the Federal Register.