# Regence

Medical Policy Manual

Laboratory, Policy No. 80

Screening Laboratory Testing

Effective: March 1, 2025

Next Review: October 2025 Last Review: October 2024

#### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### DESCRIPTION

Screening laboratory tests are performed in the absence of signs or symptoms of a disorder. They may be performed to determine the risk of developing a disease or condition, with the goal of prevention or early treatment, or to detect a disorder that is not yet symptomatic. While screening for certain conditions, such as hyperlipidemia, may be recommended for some adults, the use of the tests in this policy as screening tests is not supported by evidence.

#### MEDICAL POLICY CRITERIA

The following laboratory tests are considered **not medically necessary** when performed as screening tests in asymptomatic individuals:

- A. Antinuclear antibodies (ANA), including titer
- B. Antibodies to extractable nuclear antigens (ENA) or deoxyribonucleic acid (DNA)
- C. Calcium (total, ionized, or urine)
- D. C-reactive protein
- E. Erythrocyte sedimentation rate
- F. Estradiol (total or free)

- G. Fecal calprotectin
- H. Ferritin
- I. Gamma-glutamyl transferase (GGT)
- J. Iron and iron binding capacity
- K. Magnesium
- L. Parathyroid hormone (parathormone)
- M. Phosphate
- N. Testosterone (free, total, or bioavailable)
- O. Thyroid stimulating hormone (TSH)
- P. Transferrin

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

### **CROSS REFERENCES**

- 1. Salivary Hormone Testing for Aging and Menopause, Laboratory, Policy No. 36
- 2. Vitamin D Testing, Laboratory, Policy No. 52
- 3. <u>Measurement of Lipoprotein-Associated Phospholipase A2 (LpPLA2) in the Assessment of Cardiovascular</u> <u>Risk</u>, Laboratory, Policy No. 63
- 4. Biomarkers for Cardiovascular Disease, Laboratory, Policy No. 78
- 5. Folate Testing, Laboratory, Policy No. 79

### BACKGROUND

#### SCREENING LABORATORY TESTS

Screening tests are tests performed to detect the presence or risk of a disorder in individuals who do not have any signs of having the disorder. This differs from diagnostic testing, which is performed to determine the cause of an individual's signs and/or symptoms. Screening laboratory tests can potentially improve health outcomes for patients when the early detection of a disorder can prompt effective lifestyle changes, surveillance, or treatments. However, many laboratory tests do not have evidence supporting their use as a screening test. For a screening test to be useful, it should have the following characteristics (adapted from Givler [2024]):<sup>[1]</sup>

- The disorder tested for should have a relatively high prevalence in the population tested and significant morbidity and/or mortality.
- Identifying and treating the disorder prior to the development of symptoms can significantly reduce morbidity/mortality.
- The test should have high sensitivity and specificity, so that most cases of the disorder can be identified with a minimum of false positives.
- The test should be accessible, safe and easy.
- Effective treatment for the disorder must be available.

The United States Preventive Services Tast Force (USPSTF) provides evidence-based recommendations on the prevention of disease, including recommendations for screening

laboratory tests. Current recommendations from the USPSTF with a grade of A or B related to laboratory testing include:<sup>[2]</sup>

- screening for colorectal cancer in adults aged 45 to 49 years
- screening for hepatitis B virus (HBV) infection in adolescents and adults at increased risk for infection
- screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity
- Rh(D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care

# **EVIDENCE SUMMARY**

There were no studies identified that evaluated the risks and benefits of screening asymptomatic individuals for the laboratory tests addressed in this policy, or directly compared health outcomes between individuals who were screened and not screened.

### PRACTICE GUIDELINE SUMMARY

There are currently no evidence-based guidelines that recommend the use of the laboratory tests in this policy for the screening of asymptomatic individuals. In 2006, the USPSTF recommended routine screening for iron deficiency anemia in asymptomatic, pregnant women, but has since archived that recommendation, stating that "the current evidence is insufficient to assess the balance of benefits and harms of screening for iron deficiency and iron deficiency anemia in pregnant persons to prevent adverse maternal and infant health outcomes."<sup>[3]</sup>

# SUMMARY

Although the laboratory tests addressed in this policy may be useful for diagnosing individuals with signs or symptoms of certain disorders or diseases, the screening of asymptomatic people with these tests is not currently recommended. Therefore, the use of these laboratory tests as screening tests in the absence of signs or symptoms is considered not medically necessary.

# REFERENCES

- 1. Givler DN, Givler A. Health Screening. StatPearls. Treasure Island (FL): StatPearls Publishing. Copyright © 2024, StatPearls Publishing LLC., 2024.
- 2. U.S. Preventive Services Task Force: A and B Recommendations. [cited 9/5/2024]. 'Available from:' <u>https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations</u>.
- 3. McDonagh M, Cantor A, Bougatsos C, et al. U.S. Preventive Services Task Force Evidence Syntheses, formerly Systematic Evidence Reviews. Routine Iron Supplementation and Screening for Iron Deficiency Anemia in Pregnant Women: A Systematic Review to Update the US Preventive Services Task Force Recommendation. Rockville (MD): Agency for Healthcare Research and Quality (US), 2015.

# CODES

Codes	Number	Description
CPT	82310	Calcium; total
	82330	Calcium; ionized
	82340	Calcium; urine quantitative, timed specimen
	82670	Estradiol; total
	82681	Estradiol; free, direct measurement (eg, equilibrium dialysis)
	82728	Ferritin
	82977	Glutamyltransferase, gamma (GGT)
	83540	Iron
	83550	Iron binding capacity
	83735	Magnesium
	83970	Parathormone (parathyroid hormone)
	83993	Calprotectin, fecal
	84100	Phosphorus inorganic (phosphate);
	84105	Phosphorus inorganic (phosphate); urine
	84402	Testosterone; free
	84403	Testosterone; total
	84410	Testosterone; bioavailable, direct measurement (eg, differential precipitation)
	84443	Thyroid stimulating hormone (TSH)
	84466	Transferrin
	85651	Sedimentation rate, erythrocyte; non-automated
	85652	Sedimentation rate, erythrocyte; automated
	86038	Antinuclear antibodies (ANA);
	86039	Antinuclear antibodies (ANA); titer
	86140	C-reactive protein;
	86225	Fluorescent noninfectious agent antibody; screen, each antibody
	86235	Extractable nuclear antigen, antibody to, any method (eg, nRNP, SS-A, SS-B, Sm, RNP, Sc170, J01), each antibody
HCPCS	None	

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