Reimbursement Policy

Parathyroid Hormone, Phosphorus, Calcium, and Magnesium Testing

I. Policy Description

Parathyroid hormone (PTH), along with calcitriol and fibroblast growth factor 23 (FGF23), regulate calcium and phosphate homeostasis. PTH modulates the serum ionized calcium concentration by stimulating kidney reabsorption of calcium as well as increasing bone resorption within minutes of PTH secretion. Primary hyperparathyroidism presents itself with hypercalcemia and elevated PTH levels and is typically caused by parathyroid adenoma or hyperplasia. Secondary hyperparathyroidism is seen "in patients with kidney failure who have increased secretion of PTH [and] is related not only to gland hyperplasia and enlargement but also to reduced expression of CaSRs [calcium-sensing receptors] and, perhaps, its downstream signaling elements."[1]

Calcium is an essential metal found in its biologically relevant divalent cation (Ca^{2+}) form in vivo. It is involved in many important biological processes, including cell signaling, signal transduction, and muscle contraction. Only 45% of the plasma calcium is in the ionized form (or 'free' form), which is the physiologically active form, while the rest is bound to albumin or complexed to anions, such as phosphate or citrate.[2] Both total calcium and ionized calcium can be tested from a blood sample. Occasionally, calcium concentration is determined from a 24-hour urine sample.[3]

Phosphorus is typically used in its oxidized phosphate polyatomic ionic form (PO_4^{3-}) in vivo and is an important functional group in all classes of biomolecules—carbohydrates, proteins, lipids, and nucleic acids. The cytosol uses a phosphate-based buffer to maintain pH homeostasis. Plasma phosphorus can be in either organic or inorganic form, but the inorganic phosphates are regulated by hormones, primarily PTH. Typically, phosphate/phosphorus testing is performed on a blood sample but it can also be performed on a urine sample.[4]

Magnesium, like calcium, in vivo is in its divalent cation (Mg^{2+}) form. It is involved in many enzymatic mechanisms as well as structural functions for both proteins and nucleic acids. Magnesium is required for maintenance of bone health as well as proper nerve conduction, muscle contraction, and energy production. Currently, magnesium is tested from a blood sample or less frequently from a 24-hour urine sample. Due to the large amounts of magnesium that is filtered and the degree of reabsorption and secretion in urine levels, "magnesium levels in the urine do not correlate with either the amount of magnesium ingested or the magnesium status in the body."[5]

Reimbursement Policy

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) Serum intact parathyroid (PTH) testing **MEETS COVERAGE CRITERIA** in **any** of the following situations:

   a) For individuals with abnormal calcium levels.

   b) One time testing for the diagnosis of hypoparathyroidism for individuals with signs of hypoparathyroidism (see Note 1).

   c) For individuals with osteoporosis or low bone mass.

   d) For individuals who have undergone parathyroidectomy.

   e) One test every year for individuals diagnosed with hyperparathyroidism and who have not undergone parathyroidectomy.

   f) At the following frequency for individuals with chronic kidney disease (CKD):

For individuals with Grade 3 CKD: One test every twelve months.

      i) For individuals with Grade 4 or Grade 5 CKD: One test every three months.

   g) One time testing for individuals with multiple endocrine neoplasia type 2A (MEN2A) or familial medullary thyroid carcinoma.

   h) At the following frequency for individuals who have pseudohypoparathyroidism or related disorders (see Note 2):

      i) For individuals who are less than 18 years of age, one test every three months.

      ii) For individuals who are 18 years of age or older, one test every year.

2) Serum intact parathyroid (PTH) testing to screen for asymptomatic hyperparathyroidism **DOES NOT MEET COVERAGE CRITERIA**.

3) For individuals presenting for a wellness visit or a general exam without abnormal findings, the following tests **DO NOT MEET COVERAGE CRITERIA**:

   a) Serum, blood, or fecal magnesium testing.

b) Serum phosphorus or phosphate testing.

c) Urine phosphorus or phosphate testing.

d) Serum total calcium, serum ionized calcium, or urine calcium testing.

e) Serum parathyroid hormone testing.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

4) Testing serum for truncated parathyroid hormone metabolites (e.g., amino-terminal and carboxy-terminal fragments) **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: Signs of hypoparathyroidism:[6]

- Hypocalcemia
- Elevated serum phosphorus
- Low calcitriol
- Hypercalciuria
- Abnormal magnesium

Note 2: Conditions of pseudohypoparathyroidism and related disorders:[7]

Pseudohypoparathyroidism Type 1A (PHP1A)—due to maternal loss of function mutation at the *GNAS* coding sequence

1. Pseudohypoparathyroidism Type 1B (PHP1B)—due to methylation defect at the *GNAS* coding sequence
2. Pseudopseudohypoparathyroidism (PPHP)—due to paternal loss of function mutation at the *GNAS* coding sequence
3. Progressive Osseous Heteroplasia (POH)—due to paternal loss of function mutation at the *GNAS* coding sequence

4. Acrodysostosis (ACRDYS1)—due to mutation in *PRKAR1A*

5. Acrodysostosis (ACRDYS2)—due to mutation in *PDE4D*

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: http://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82310	Calcium; total
82330	Calcium; ionized
82340	Calcium; urine quantitative, timed specimen
83735	Magnesium
83970	Parathormone (parathyroid hormone)
84100	Phosphorus inorganic (phosphate)
84105	Phosphorus inorganic (phosphate); urine

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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