

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

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|----------------|---|-----------------------|--|
| POLICY: | Complications Secondary to Chronic Kidney Disease | P&T DATE: | 12/11/2018 |
| CLASS: | Renal Disease/Genitourinary Disorders | REVIEW HISTORY | 12/17, 5/17, 12/16, 2/16, 11/15, 9/15, 9/14, 5/10, 12/07 |
| LOB: | Medi-Cal | (MONTH/YEAR) | |

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Chronic kidney disease (CKD) is a public health problem with an overall prevalence of 14% in the United States.¹ It is associated with poor prognosis and high healthcare costs and may lead to complications that result in higher hospitalizations, morbidity, and mortality rates. Disorders of renal tubular reabsorption and secretion can cause electrolyte disturbances, which are markers of kidney damage. These include hyperphosphatemia, hyperkalemia, hyponatremia, and hypocalcemia. Consequently, hyperphosphatemia and vitamin D deficiency/hypocalcemia may lead to secondary hyperparathyroidism. Electrolyte imbalances in the body can be detrimental and cause serious complications if untreated; therefore, they must be managed accordingly to improve health outcomes.

Another complication secondary to CKD is hypoalbuminemia. This policy is supplemental to the PH-19 Nutritional Supplements for Medical Conditions HPSJ Policy but is specific for the supplements that are preferred for use in persons with CKD experiencing hypoalbuminemia.

In summation, PH-19 states the following regarding oral or enteral nutrition supplements:

- Enteral nutrition supplements or replacements are only covered through the Medi-Cal pharmacy benefit when used as a medically necessary therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the use of regular food.
- Nutritional supplements are not medically necessary when the criteria are not met or if use of the supplements are based on convenience or preference of the member or provider.
- Infant formula for normal healthy infants is a specifically excluded benefit under the Medi-Cal, California Children's Services (CCS), or Genetically Handicapped Persons Program, those who are eligible under WIC will be referred to WIC.

The purpose of this coverage policy is to review medication and nutritional agents used specifically for the treatment or management of complications secondary to CKD. If nutritional supplementation is needed for any other cases not related to CKD, please refer to PH-19 – Nutritional Supplements for Medical Conditions policy.

TABLE 1: Oral Electrolyte Disorder Agents Formulary Positioning: (Current as of 12/2018)

| Therapeutic Class | Generic Name (Brand Name) | Available Strengths | Formulary Limits | Average Cost* per 30 days | Notes |
|------------------------------------|--|---------------------------------|------------------|---------------------------|--|
| HYPERPHOSPHATEMIA | | | | | |
| Phosphate Binders | Calcium Acetate (Phoslo, Calphron, Eliphos, Phoslyra) | <u>Tablet:</u> 667 mg | -- | \$59.97 | Calcium Acetate capsules/gelcaps are reserved for documented intolerance to tablets. |
| | | <u>Capsule:</u> 667 mg | PA | | |
| | | <u>Oral Solution:</u> 667mg/5mL | NF | | |
| | Sevelamer Carbonate (Renvela) | <u>Tablet:</u> 800 mg | PA | \$446.58 | |
| <u>Powder packet:</u> 0.8 g, 2.4 g | | PA | \$1,066.98 | | |

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|---------------------------------|--|--|------------|------------|---|
| | Sevelamer Hydrochloride (Renagel) | <u>Tablet:</u> 400 mg, 800 mg | PA | \$1,792.75 | Reserved for treatment failure or have documented intolerance to Renvela (Sevelamer Carbonate). |
| | Lanthanum Carbonate (Fosrenol) | <u>Chewable tablet:</u> 500 mg, 750 mg 1000 mg | PA, QL | \$1,369.57 | Third line therapy for patients with treatment failure of Calcium Acetate and Sevelamer. Fosrenol 500 mg and 750 mg tablets are limited to 3 tablets per day of each strength. |
| | Ferric Citrate (Auryxia) | <u>Tablet:</u> 210 mg | NF | \$1,294.80 | |
| | Sucroferric Oxyhydroxide (Velporo) | <u>Tablet:</u> 500 mg | NF | \$1,738.32 | |
| HYPERPARATHYROIDISM | | | | | |
| Vitamin D Analogs | Calcitriol (Calcijex, Rocaltrol) | <u>Capsule:</u> 0.25 mcg 0.5 mcg | -- | \$9.27 | Calcitriol 0.5mcg capsules are NON-FORMULARY. |
| | | <u>Oral Solution:</u> 1 mcg/mL | PA | \$98.60 | Reserved for use in CKD with documented inability to swallow calcitriol capsules. |
| | Paricalcitol (Zemlar) | <u>Capsule:</u> 1 mcg, 2 mcg, 4 mcg | PA | \$342.68 | Reserved for patients who have failed Calcitriol. |
| | Doxercalciferol (Hectorol) | <u>Capsule:</u> 0.5 mcg, 1 mcg, 2.5 mcg | NF | -- | |
| Calcimimetics | Cinacalcet (Sensipar) | <u>Tablet:</u> 30 mg, 60 mg, 90 mg | PA, QL, SP | \$1,232.96 | Step therapy to patients with secondary hyperparathyroidism with BiPTH > 200 pg/ml despite compliant use of phosphate binders or with CKD-5D. Sensipar 30 mg and 60 mg tablets are limited to two tablets per day of each strength. |
| HYPERKALEMIA | | | | | |
| Cation-Exchange Resins | Sodium Polystyrene Sulfonate (Kayexalate, Kalexate, Kionex) | <u>Oral suspension:</u> 15 g/60 mL | -- | \$98.71 | |
| | | <u>Rectal enema:</u> 30 g/120 mL | PA | \$48.20 | For hyperkalemia in patients with vomiting not successfully treated by oral anti-nausea medications, or have upper GI problems. |
| | Patiromer (Veltassa) | <u>Powder packet:</u> 8.4 g, 16.8 g, 25.2 g | PA, QL | \$742.51 | For hyperkalemia in patients at risk for colonic necrosis, hypernatremia, or have heart failure. Limited to 1 packet per day per strength. |
| HYPONATREMIA | | | | | |
| ADH Receptor Antagonists | Tolvaptan (Samsca) | <u>Tablet:</u> 15 mg, 30 mg | NF | -- | |

PA = Prior Authorization; QL = Quantity limit; SP = Specialty Pharmacy; NF = Non-Formulary

*Based on standard rates and standard dosing

TABLE 2: Formulary Preferred Nutritional Supplements for CKD (Current as of 12/2018)

| Enteral/Oral Product | Serving Size | Unit | Protein (g) per Serving | Calories (kcal) per Serving | Avg Daily Servings | Avg Daily Protein | Restrictions |
|-----------------------|--------------|------|-------------------------|-----------------------------|--------------------|-------------------|--------------|
| FIBERSOURCE HN LIQUID | 250 | mL | 13.5 | 300 | 6 | 80 | PA |
| JEVITY 1 CAL LIQUID | 237 | mL | 10.4 | 250 | 5 | 55 | PA |

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|--------------------------|-----|----|------|-----|---|-----|----|
| JEVITY 1.2 CAL LIQUID | 237 | mL | 13.2 | 285 | 6 | 76 | PA |
| JEVITY 1.5 CAL LIQUID | 237 | mL | 15.1 | 355 | 5 | 70 | PA |
| NEPRO CARB STEADY LIQUID | 237 | mL | 19.1 | 425 | 3 | 57 | PA |
| NUTREN 1.0 LIQUID | 250 | mL | 10 | 250 | 5 | 51 | PA |
| NUTREN 1.5 LIQUID | 250 | mL | 17 | 375 | 6 | 101 | PA |
| NUTREN 2.0 LIQUID | 250 | mL | 20 | 500 | 4 | 71 | PA |

Avg = Average, PA = Prior Authorization required

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Vitamin D Analogs

Calcitriol (Calcijex, Rocaltrol); Paricalcitol (Zemlar)

Calcitriol (Calcijex, Rocaltrol)

- Coverage Criteria:**
 - Calcitriol 0.25 mcg capsule: None
 - Calcitriol 1mcg/mL solution: Reserved for use in chronic kidney disease with documented inability to swallow calcitriol capsules.
- Limits:** None
- Required Information for Approval:** For the solution, documentation of inability to swallow calcitriol capsules.
- Other notes:** None
- Non-formulary:**
 - Calcitriol 0.5mcg capsules

Paracalcitol (Zemlar)

- Coverage Criteria:** Reserved for patients who have failed Calcitriol.
- Limits:** None
- Required Information for Approval:** Medication fill history showing patient has tried Calcitriol at any point.
- Other notes:** None

Calcimimetics

Cinacalcet (Sensipar)

- Coverage Criteria:** Reserved for patients with secondary hyperparathyroidism with BiPTH > 200 pg/ml despite compliant use of phosphate binders or with CKD-5D.
- Limits:** PA required.
- Required Information for Approval:** Medication fill history showing continuous fills of phosphate binders OR CKD-5D AND clinic notes or laboratory data showing patient has BiPTH > 200 pg/mL.
- Other notes:**
 - Restricted to specialty pharmacy.
 - Sensipar 30 mg tablets are limited to 2 tablets per day.
 - Sensipar 60 mg tablets are limited to 2 tablets per day.
 - Parsabiv (Etelcalcetide) is non-formulary.

Phosphate Binders

Calcium Acetate (Phoslo, Phoslyra, Calphron, Eliphos); Sevelamer Carbonate (Renvela); Sevelamer HCl (Renagel); Lanthanum Carbonate (Fosrenol)

Calcium Acetate (Phoslo, Phoslyra, Calphron, Eliphos)

- Coverage Criteria:**
 - Calcium Acetate Capsules/Gelcaps: Reserved for treatment failure to calcium acetate tablets and have documented inability to swallow tablets.

- Limits:** PA required for Calcium Acetate Capsules/Gelcaps.
- Required Information for Approval:** N/A
- Other Notes:**
 - First-line treatment for hyperphosphatemia.
 - Concurrent use of Vitamin D helps with absorption of calcium.
 - Phoslyra is non-formulary.

Sevelamer Carbonate (Renvela), Sevelamer HCl (Renagel)

- Coverage Criteria:**
 - **Sevelamer Carbonate Tablets:** Second line treatment for hyperphosphatemia after Calcium Acetate, unless on dialysis, corrected serum calcium > 10.2 mg/dl, or evidence of soft tissue calcification.
 - **Sevelamer Packets:** Must have documented inability to swallow Sevelamer Tablets.
 - **Renagel tablets:** Reserved for treatment failure or have documented intolerance to Renvela (Sevelamer Carbonate).
- Limits:** PA required.
- Required Information for Approval:**
 - **Sevelamer Carbonate Tablets:** Fill history of Calcium Acetate OR one of the following: on dialysis, corrected serum calcium > 10.2 mg/dl, or evidence of soft tissue calcification.
 - **Sevelamer Packets:** Inability to swallow Sevelamer Tablets.
 - **Renagel tablets:** Fill history of Sevelamer Carbonate or documented intolerance to Sevelamer Carbonate.
- Other Notes:** None

Lanthanum Carbonate (Fosrenol)

- Coverage Criteria:** Third line therapy for patients with treatment failure of Calcium Acetate and Sevelamer.
- Limits:** PA required.
- Required Information for Approval:** Medication fill history showing patient has tried Calcium Acetate and Sevelamer in the past.
- Other Notes:**
 - Fosrenol 500mg tablets are limited to 3 tablets per day.
 - Fosrenol 750mg tablets are limited to 3 tablets per day.

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| Cation-Exchange Resins |
| <i>Sodium Polystyrene Sulfonate (Kayexalate, Kalexate, Kionex); Patiromer (Veltassa)</i> |

Sodium Polystyrene Sulfonate (Kayexalate, Kalexate, Kionex)

- Coverage Criteria:**
 - SPS Solution: None
 - SPS Rectal Enemas: Reserved for patients with vomiting not successfully treated by oral anti-nausea medications, or have upper GI problems, including paralytic ileus.
- Limits:**
 - SPS Solution: None
 - SPS Rectal Enemas: PA required.
- Required Information for Approval:** For approval of rectal enemas, documentation of past anti-nausea medications tried and/or history of upper GI problems.
- Other Notes:** None

Patiromer (Veltassa)

- Coverage Criteria:** Reserved for patients with Potassium >5.5 mEq/L AND one of the following: at risk of colonic necrosis (impaction, chronic constipation, inflammatory bowel disease, ischemic colitis, vascular intestinal atherosclerosis, or bowel obstruction), OR Hypernatremia, OR Diagnosis of Heart Failure.
- Limits:** Limited to 1 packet per day per strength.
- Required Information for Approval:** Labs showing potassium (K⁺) > 5.5 mEq/L AND one of the following: Clinic notes documenting risk for colonic necrosis, labs documenting hypernatremia, or diagnosis of heart failure.
- Other Notes:** None

Nutritional Supplements for Hypoalbuminemia in CKD

Fibersource, Jevity, Nepro, Nutren

❑ Coverage Criteria:

- **Chronic Kidney Disease:** – Reserved for ESRD patients diagnosed with malnutrition that cannot meet nutritional needs through a standard diet and able to meet the criteria of use for medical necessity.
 - Patients with protein-energy wasting, meeting at least 1 of the following criteria:
 - Serum albumin < 3.8 g/dL (3-month rolling average)
 - BMI < 18.5 kg/m²
 - Unintentional weight loss (≥ 5% over 1 month; ≥7.5% over 3 mos.; or ≥ 10% over 6 mos.)
- AND**
- Clinical record showing patient has failed oral nutritional supplements OR documentation of use of an enteral feeding tube.

❑ Limits:

- Maximum of 6 months (initial use).
- Continuation of therapy only after demonstrated benefit of enteral/parenteral nutrition for at least 3-rolling months. Maximum of 1 year.

❑ Required Information for Approval:

- Documentation of high nutrient requiring disease state
- Diagnosis of malnutrition that cannot meet needs through a standard diet
- Meets medical necessity criteria as stated above and as stated in PH-19
- Clinical record of failing oral nutritional supplements OR documentation of an enteral feeding tube
- Meets protein-energy wasting criteria (1 of the following):
 - Serum albumin < 3.8 g/dL (3-month rolling average)
 - BMI < 18.5 kg/m²
 - Unintentional weight loss (≥ 5% over 1 month; ≥7.5% over 3 mos.; or ≥ 10% over 6 mos.)

❑ Notes:

- **Above criteria will also be used when considering other high nutrient requirement disease states.**
- **All intradialytic parenteral nutrition (IDPN) are NON-FORMULARY** – Reserved for patients who have documented diagnosis of a GI disorder (e.g. gastroparesis, malabsorption) OR cannot be maintained on enteral feedings (patient can meet ≥ 50% of nutritional needs orally and has not been able to increase oral intake with supplements, whereupon enteral nutrition consists of < 50% of the total dietary intake).

Clinical Justification:

HYPERPHOSPHATEMIA AND HYPERPARATHYROIDISM

HPSJ's coverage policy for electrolyte disorders secondary to CKD, specifically hyperphosphatemia and hyperparathyroidism, is based on recommendations by the National Kidney Foundation (NKF) Kidney Disease Outcome and Quality Initiative (K/DOQI) and Kidney Disease, Improving Global Outcomes (KDIGO). Hyperphosphatemia and hyperparathyroidism are two common complications that arise from CKD, so it is crucial to treat them accordingly. Serum phosphorus, calcium, vitamin D, and parathyroid (PTH) concentrations are all correlated to each other, so treatment of disorders of each parameter requires evaluation of the other parameters. KDIGO guidelines recommend the evaluation and treatment for hyperphosphatemia, hypocalcemia, and vitamin D deficiency in patients with intact parathyroid (PTH) levels above the upper limit normal. The guidelines recommend calcium- and non-calcium-containing phosphate binders for the treatment of hyperphosphatemia, and vitamin D analogs and calcimimetics for the treatment of severe and progressive secondary hyperparathyroidism.

HYPERKALEMIA

The current treatments available to treat hyperkalemia include reduction of dietary potassium intake, modification of contributing medications, and use of cation-exchange resins [e.g., Sodium Polystyrene Sulfonate (SPS) and Patiromer]. SPS has historically been used in the treatment of hyperkalemia, but its use is limited by (1) questionable efficacy in reducing serum potassium levels, (2) poor gastrointestinal (GI) tolerability, and (3) rare occurrences of colonic necrosis. Newer agents, such as Patiromer, have shown adequate efficacy in clinical trials in lowering elevated potassium levels with better side effect profiles than SPS.

HYPONATREMIA

The American Academy of Family Physicians (AAFP) recommends treatment with 3% saline for severe symptomatic hyponatremia. Vaptans may also be used for hospitalized patients with clinically significant euvolemic and hypervolemic hyponatremia, but the AAFP recommends against their routine use. In the United States, the only available vaptans are oral Tolvaptan (Samsca®) and intravenous Conivaptan (Vaprisol®).

HYPOALBUMINEMIA/MALNUTRITION

Albuminuria levels are used to categorize CKD severity, progression, and prognosis. Patients with proteinuria at any stage of CKD are recommended to be referred to a Renal Dietitian/Nutritionist. Per the Academy of Nutrition and Dietetics, it is recommended to prescribe persons with CKD a protein-controlled diet providing 0.8g to 0.9g of protein per kg of body weight per day. Protein intake lower than the recommended amount may result in hypoalbuminemia. Patients who meet medical necessity criteria for oral or enteral nutritional supplementation can choose from the above formulary agents in Table 2 as they are available in either cans or enteral packages, vary in grams of protein, and vary in calories per serving to meet the needs of different daily protein and calorie requirements.

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✚ REVIEW & EDIT HISTORY

| Document Changes | Reference | Date | P&T Chairman |
|--|---|---------|---------------------------------|
| Creation of Policy | UM 59 – Nutritional Supplements.pdf | 12/2007 | Allen Shek, PharmD, BCPS |
| Creation of Policy | Phosphate Binder 5-18-10.doc | 05/2010 | Allen Shek, PharmD, BCPS |
| Update to Policy | UM 59 - Therapeutic Enteral Formula for Medical Conditions in Infants and Children.docx | 9/2014 | Jonathan Szkotak, PharmD, BCACP |
| Update to Policy | PH19 - Nutritional Supplements for Medical Conditions 09-2015.docx | 9/2015 | Jonathan Szkotak, PharmD, BCACP |
| Update to Policy | Drug Class Review - Nutrition in ESRD 2015-11.docx | 11/2015 | Johnathan Yeh, PharmD |
| Update to Policy | PH-19 – Nutritional Supplements for Medical Conditions 2-2016.docx | 2/2016 | Johnathan Yeh, PharmD |
| Update to Policy | HPSJ Coverage Policy – Renal – Complications Secondary to CKD 2016-12.docx | 12/2016 | Johnathan Yeh, PharmD |
| Creation of Policy | HPSJ Coverage Policy - Gastrointestinal Disorders - Nutrition 2017-05 | 5/2017 | Johnathan Yeh, PharmD |
| Update to Policy | HPSJ Coverage Policy – Renal – Complications Secondary to CKD 2017-12.docx | 12/2017 | Johnathan Yeh, PharmD |
| Update to and Merging of Complications and Nutrition in CKD Policies | HPSJ Coverage Policy – Renal – Complications Secondary to CKD 2018-12.docx | 12/2018 | Matthew Garrett, PharmD |

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy.