Clinical Policy: Somatropin (Recombinant Human Growth Hormone)
Reference Number: ERX.SPA.14
Effective Date: 07.01.16
Last Review Date: 05/17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Somatropin (Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, Zomacton™, Zorbtive®) is a recombinant human growth hormone (rhGH).

FDA approved indication
Somatropin is indicated:

- For the treatment of children with:
  - Growth failure due to inadequate endogenous growth hormone (GH) secretion
  - Prader-Willi syndrome
  - Short stature associated with Turner syndrome
  - Short stature associated with Noonan syndrome
  - Short stature or growth failure associated with SHOX deficiency
  - Growth failure in children born small for gestational age who fail to manifest catch-up growth by 2-4 years of age
  - Growth failure associated with chronic renal insufficiency (CRI) up until the time of renal transplantation
  - Idiopathic short stature (non-GH-deficient short stature) defined by height SDS ≤ -2.25 and growth rates unlikely to permit attainment of adult height in the normal range
- For the treatment of adults with:
  - Growth hormone deficiency (GHD)
    - Adult-onset (AO): Patients who have GH deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
    - Childhood-onset (CO): Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes
      Patients who were treated with somatropin for GH deficiency in childhood and whose epiphyses are closed should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for GH deficient adults. According to current standards, confirmation of the diagnosis of adult GH deficiency in both groups involves an appropriate GH provocative test with two exceptions: (1) patients with multiple other pituitary hormone deficiencies due to organic disease; and (2) patients with congenital/genetic GH deficiency
  - Short bowel syndrome in patients receiving specialized nutritional support
  - HIV in patients with wasting or cachexia with concomitant antiviral therapy

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that somatropin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neonatal Hypoglycemia (must meet all)**:**

1. Diagnosis of neonatal hypoglycemia;

2. Prescribed by or in consultation with an endocrinologist;
3. Brain MRI shows risk for hypopituitarism;
4. Random growth hormone (GH) measurement of < 20 µg/L;
5. Causes of hypoglycemia, other than growth hormone deficiency (GHD), have been ruled out;
6. Dose does not exceed 0.4 mg/kg/week;
7. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: up to 12 months total

B. Neonatal Hypoglycemia (must meet all)**:**

1. Diagnosis of GHD;
2. Prescribed by or in consultation with an endocrinologist;
3. Evidence of short stature/growth failure per Appendix B;
4. Other causes of growth failure have been ruled out (e.g., chronic systemic disease, undernutrition, hypothyroidism, Turner syndrome - in girls, skeletal disorders);
5. Intracranial tumor is excluded by MRI or CT;
6. Low or low normal IGF-I or IGFBP-3 level and one of the following (a, b, c, d, or e):
   a. Two GH stimulation tests with peak levels ≤ 10 µg/mL;
   b. Evidence of ≥ 3 pituitary hormone deficiencies;
   c. History of surgery or irradiation in the hypothalamic-pituitary region;
   d. Defined central nervous system pathology documented by MRI or CT;
   e. Documented genetic cause of GHD;
7. Dose does not exceed either of the following:
   a. 0.7 mg/kg/week if pubertal;
   b. 0.4 mg/kg/week if non-pubertal;
8. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: 12 months

C. Growth Hormone Deficiency – Adults and Transition Patients (must meet all)**:**

1. Diagnosis of adult onset (AO) or childhood onset (CO) GHD;
2. Prescribed by or in consultation with an endocrinologist;
3. One of the following (a, b, or c):
   a. Two GH stimulation tests with peak levels ≤ 5 µg/mL;
   b. Both of the following (i and ii):
      i. One GH stimulation test with a peak level ≤ 5 µg/ml;
      ii. One low IGF-I level;
   c. One low IGF-I level and one of the following (i, ii, or iii):
      i. Hypothalamic-pituitary structural lesions;
      ii. Evidence of ≥ 3 pituitary hormone deficiencies;
      iii. Documented genetic cause of GHD;
4. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: 12 months

D. Genetic Diseases with Primary Effects on Growth - Children (must meet all)**:**

1. Member has one of the following diagnoses (a, b, c, or d):
   a. Prader-Willi syndrome (PWS) (i and ii):
      i. Confirmed by genetic testing;
      ii. Dose does not exceed 0.3 mg/kg/week;
   b. Turner syndrome (i, ii, and iii):
      i. Confirmed by genetic testing;

ii. Evidence of short stature or growth failure per Appendix C;
iii. Dose does not exceed 0.5 mg/kg/week;
c. Noonan syndrome (i, ii, and iii):
i. Confirmed by genetic testing or diagnosed by a geneticist;
ii. Evidence of short stature or growth failure per Appendix C;
iii. Dose does not exceed 0.5 mg/kg/week;
d. Short stature homeobox-containing gene (SHOX) deficiency (i, ii, and iii):
i. Confirmed by genetic testing;
ii. Evidence of short stature or growth failure per Appendix C;
iii. Dose does not exceed 0.4 mg/kg/week;
2. Prescribed by or in consultation with an endocrinologist;
3. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: 12 months

E. Prader-Willi Syndrome - Adults and Transition Patients (must meet all)**:**
1. Diagnosis of PWS confirmed by genetic testing;
2. Prescribed by or in consultation with an endocrinologist;
3. rGH therapy will be titrated to maintain normal range IGF-1 level for age and sex matched controls;
4. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: 12 months

F. Born Small for Gestational Age - Children (must meet all)**:**
1. Diagnosed as small for gestational age (SGA);
2. Prescribed by or in consultation with an endocrinologist;
3. Birth weight or length > 2 SD below the mean for gestational age;
4. Failure to manifest catch-up growth to reach normal height range by age 2;
5. Dose does not exceed 0.5 mg/kg/week;
6. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: 12 months

G. Chronic Kidney Disease - Children (must meet all)**:**
1. Diagnosis of chronic kidney disease (CKD) as evidenced by one of the following (a, b, or c):
a. Structural or functional abnormalities of the kidney for ≥ 3 months;
b. GFR < 60 mL/min per 1.73 m^2 for ≥ 3 months;
c. Occurrence of a and b together of any duration;
2. Prescribed by or in consultation with an endocrinologist;
3. Evidence of short stature or growth failure per Appendix C;
4. Prescribed in conjunction with optimal CKD management (e.g., metabolic, endocrine and nutritional abnormalities have been treated and stabilized);
5. Member does not have a functioning renal allograft;
6. Dose does not exceed 0.4 mg/kg/week;
7. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: 12 months

H. Short Bowel Syndrome - Adults (must meet all)**:**
1. Diagnosis of short bowel syndrome (SBS);
2. Prescribed by or in consultation with an endocrinologist;

3. Age ≥ 18 years;
4. Member's SBS therapeutic plan requires specialized nutritional support;
5. Dose does not exceed 8 mg/day;
6. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: 3 months

I. HIV-Related Wasting or Cachexia - Adults (must meet all)**:**
1. Diagnosis of HIV-related wasting or cachexia;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Unexplained weight loss of > 10% body weight from baseline;
5. Treatment with therapies other than rhGH have been suboptimal;
6. Alternate causes of wasting or cachexia have been ruled out;
7. Currently receiving antiretroviral therapy;
8. Dose does not exceed 6 mg/day;
9. If prescription is for an rhGH product other than Norditropin or Humatrope, the Norditropin and Humatrope formulations are inappropriate (e.g., due to preservatives or dosing increment limitations) or member has a contraindication or intolerance to Norditropin and Humatrope.

Approval duration: up to 3 months total

J. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Neonatal Hypoglycemia (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 0.4 mg/kg/week.

Approval duration: up to 12 months total

B. Growth Hormone Deficiency - Children (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy;
3. If treatment for ≥ 1 year, both of the following (a and b):
   a. Height velocity > 2 cm/year;
   b. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. If request is for a dose increase, new dose does not exceed:
   a. If pubertal - 0.7 mg/kg/week;
   b. If non-pubertal - 0.4 mg/kg/week.

Approval duration: 12 months

C. Growth Hormone Deficiency - Adults (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy;
3. Normalization of IGF-1 levels if low prior to rhGH therapy;
4. One of the following (a, b, c, or d):
   a. Decreased body fat;
   b. Increased bone density;
   c. Improved endurance;
   d. Less fatigue.

Approval duration: 12 months

D. Genetic Diseases with Primary Effects on Growth - Children (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy;
3. If treatment for ≥ 1 year, both of the following (a and b):
   a. Height velocity > 2 cm/year;
   b. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. If request is for a dose increase, new dose does not exceed:
   a. PWS - 0.3 mg/kg/week;
   b. Turner syndrome - 0.5 mg/kg/week;
   c. SHOX deficiency - 0.4 mg/kg/week;
   d. Noonan syndrome - 0.5 mg/kg/week.

Approval duration: 12 months

E. Prader-Willi Syndrome – Adults and Transition Patients (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy (e.g., positive effects on body composition, lipid metabolism, physical and psychosocial functioning relative to potential side effects including impairments of glucose metabolism, edema or heart disease);
3. IGF-1 is within the normal range for age and sex.

Approval duration: 12 months

F. Born Small for Gestational Age - Children (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy;
3. If treatment for ≥ 1 year, both of the following (a and b):
   a. Height velocity > 2 cm/year;
   b. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. If request is for a dose increase, new dose does not exceed 0.5 mg/kg/week.

Approval duration: 12 months

G. Chronic Kidney Disease – Children (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy;
3. If treatment for ≥ 1 year, both of the following (a and b):
   a. Height velocity > 2 cm/year;
   b. Bone age ≤ 15 years if girl or ≤ 17 years if boy;
4. If request is for a dose increase, new dose does not exceed 0.4 mg/kg/week;
5. Member does not have a functioning renal allograft.

Approval duration: 12 months

H. Short Bowel Syndrome: Adults (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy;
3. Decreased specialized nutritional requirement as measured by total volume, total calories, or infusion frequency;
4. If request is for a dose increase, new dose does not exceed 8 mg/day.

Approval duration: up to 6 months total

I. HIV-Related Wasting or Cachexia: Adults (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of adherence and positive response to therapy;
3. One of the following (a, b, or c):
   a. Partial recovery of weight loss documented at baseline;
   b. Improvement in body mass;
   c. Improvement in nutritional status;
4. Currently receiving antiretroviral therapy;
5. If request is for a dose increase, new dose does not exceed 6 mg/day.

Approval duration: up to 3 months total

J. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents
B. Idiopathic short stature
C. Constitutional growth delay
D. Obesity
E. Adult short stature or altered body habitus associated with antiviral therapy
F. Anabolic therapy to enhance body mass or strength for non-medical reasons (e.g., athletic gains)

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AO: adult onset
CO: childhood onset
CKD: chronic kidney disease
FDA: Food and Drug Administration
GFR: glomerular filtration rate
GH: growth hormone
GHD: growth hormone deficiency
HGH: human growth hormone
HIV: human immunodeficiency virus
ISS: idiopathic short stature
PWS: Prader-Willi syndrome
SBS: short bowel syndrome
SD: standard deviation
SGA: small for gestational age
SHOX deficiency: short stature homeobox-containing gene deficiency

Appendix B: Short Stature/Growth Failure Criteria
Short stature/growth failure prior to rhGH therapy is evidenced by one of the following:
1. Height > 3 SD below the mean
2. Height > 2 SD below the mean and (a or b)
   a. Height velocity > 1 SD below the mean over 1 year
   b. Decrease in height SD > 0.5 over 1 year in children > 2 years of age
3. Height > 1.5 SD below midparental height
4. Height velocity > 2 SD below the mean over 1 year
5. Height velocity > 1.5 SD below the mean over 2 years

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Genotropin	Pediatric GHD	0.16 to 0.24 mg/kg/week SC	0.24 mg/kg/week
	Prader-Willi syndrome	0.24 mg/kg/week SC	Based on weight
	Turner syndrome	0.33 mg/kg/week SC	Based on weight
	SGA	Up to 0.48 mg/kg/week SC	Based on weight
	Adult GHD	Non-weight based: 0.2 mg/day SC (range 0.15-0.3 mg/day) Weight based: 0.04 mg/kg/week SC	Non-weight based: 0.3 mg/day Weight based: 0.8 mg/kg/week
Humatrope	Pediatric GHD	0.18 to 0.30 mg/kg/week SC	Based on weight
	Turner syndrome	Up to 0.375 mg/kg/week SC	Based on weight
	SHOX deficiency	0.35 mg/kg/week SC	Based on weight
	SGA	Up to 0.47 mg/kg/week SC	Based on weight
	Adult GHD	Non-weight based: 0.2 mg/day SC (range 0.15-0.3 mg/day) Weight based: 0.006 mg/kg/day SC	Non-weight based: 0.3 mg/day Weight based: 0.0125 mg/kg/day
Norditropin	Pediatric GHD	0.024 to 0.034 mg/kg/day, 6 to 7 times a week SC	Based on weight
	Noonan syndrome	Up to 0.066 mg/kg/day SC	Based on weight
	Turner syndrome	Up to 0.067 mg/kg/day SC	Based on weight
	SGA	Up to 0.067 mg/kg/day SC	Based on weight
	Adult GHD	Non-weight based: 0.2 mg/day SC (range 0.15-0.3 mg/day) Weight based: 0.004 mg/kg/day SC	Non-weight based: 0.3 mg/day Weight based: 0.016 mg/kg/day
Nutropin AQ	Pediatric GHD	Non-pubertal: up to 0.3 mg/kg/week SC Pubertal: up to 0.7 mg/kg/week SC	Based on weight
	Chronic kidney disease	Up to 0.35 mg/kg/week SC	Based on weight
	Turner syndrome	Up to 0.375 mg/kg/week SC	Based on weight
	Adult GHD	Non-weight based: 0.2 mg/day SC (range 0.15-0.3 mg/day) Weight based: 0.006 mg/kg/day SC	Non-weight based: 0.3 mg/day Weight based: 0.025 mg/kg/day in patients ≤ 35 years old; 0.0125 mg/kg/day in patients > 35 years old
Omnitrope	Pediatric GHD	0.16 to 0.24 mg/kg/week SC, divided into 6 to 7 daily injections	Based on weight
	Prader-Willi syndrome	0.24 mg/kg/week SC, divided into 6 to 7 daily injections	Based on weight
	Turner syndrome	0.33 mg/kg/week SC, divided into 6 to 7 daily injections	Based on weight

	SGA	Up to 0.48 mg/kg/week SC, divided into 6 to 7 daily injections	Based on weight
	Adult GHD	0.04 mg/kg/week SC (divided into daily injections)	0.08 mg/kg/week
Saizen	Pediatric GHD	0.18 mg/kg/week, divided into equal doses given either on 3 alternate days, 6 times per week or daily	Based on weight
	Adult GHD	Non-weight based: 0.2 mg/day SC (range 0.15-0.3 mg/day) Weight based: 0.005 mg/kg/day SC	0.01 mg/kg/day
Serostim	HIV with wasting or cachexia	0.1 mg/kg/day SC at bedtime	6 mg/day
Zomacton	Pediatric GHD	0.1 mg/kg SC 3 times per week	0.3 mg/kg/week
Zorbtive	Short bowel syndrome	0.1 mg/kg/day SC	8 mg/day

VI. Product Availability

Drug	Availability
Genotropin	Cartridge: 5 mg, 12 mg MiniQuick: 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg, 2 mg
Humatrope	Vial: 5 mg Cartridge: 6 mg, 12 mg, 24 mg
Norditropin	FlexPro pen: 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5 mL, 30 mg/3 mL
Nutropin AQ	NuSpin: 5 mg/2 mL, 10 mg/2 mL, 20 mg/2 mL Pen cartridge: 10 mg/2 mL, 20 mg/2 mL
Omnitrope	Pen: 5 mg/1.5 mL, 10 mg/1.5 mL Vial: 5.8 mg
Saizen	Vial: 5 mg, 8.8 mg Click.Easy: 8.8 mg
Serostim	Vial: 4 mg, 5 mg, 6 mg
Zomacton	Vial: 5 mg, 10 mg
Zorbtive	Vial: 8.8 mg

VII. References

1. Genotropin Prescribing Information. New York, NY: Pfizer Inc.; May 2015.
2. Humatrope Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2015.
3. Norditropin Prescribing Information. Princeton, NJ: Novo Nordisk Inc.; January 2015
4. Nutropin AQ Prescribing Information. South San Francisco, CA: Genentech, Inc.; June 2014.
5. Omnitrope Prescribing Information. Princeton, NJ: Sandoz Inc.; October 2014.
6. Saizen Prescribing Information. Rockland, MA: EMD Serono Inc.; June 2014.
7. Serostim Prescribing Information. Rockland, MA: EMD Serono Inc.; October 2015.
8. Zomacton Prescribing Information. Horsham, PA: Teva Pharmaceuticals USA, Inc.; June 2015.
9. Zorbtive Prescribing Information. Rockland, MA: EMD Serono Inc.; January 2012.
10. GH Research Society. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCEM. 2000; 85(11): 3990-3993.
11. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr. 2003; 143: 415-421.

12. Cook DM, Yuen KCJ, Biller BMK, et al. American Association of Clinical Endocrinologists. Medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients - 2009 update. Endocr Pract. 2009; 15(2): 1-28.
13. Molitch ME, Clemmons DR, Malozowski S, et al. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011; 96: 1587-1609.
14. Deal CL, Tony M, Hoybye C, et al. Growth Hormone Research Society workshop summary: Consensus guidelines for recombinant human growth hormone therapy in Prader-Willi Syndrome. JCEM. 2013; 98(6): E1072-E1087. doi: 10.1210/jc.2012-3888.
15. Clayton PE, Cianfarani S, Czernichow G, et. al. Management of the child born small for gestational age through to adulthood: a consensus statement of the International Societies of Pediatric Endocrinology and the Growth Hormone Research Society. JCEM. 2007; 92(3): 804-10.
16. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. National Kidney Foundation. Am J Kidney Dis. 2002; 39(2 Suppl 1): S1.
17. Nemecheck PM, Polsky B, Gottlieb MS. Treatment Guidelines for HIV-Associated Wasting. Mayo Clin Proc. 2000; 75: 386-394.
18. Somatropin. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed May 20, 2016.
19. Wong CS, Warady BA, Srivastava T. Clinical presentation and evaluation of chronic kidney disease in children. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed May 22, 2016.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06/16	06/16
Added criteria for adult and transition PWS to initial and continuation criteria per the GH Research Society PWS 2013 consensus statement.	09/16	09/16

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.