TITLE: SOMATROPIN (HUMATROPE®, NUTROPIN/NUTROPIN AQ®, SAIZEN®, TEVTROPIN®, SEROSTIM®, ZORBTIVE®, GENOTROPIN®, NORDITROPIN®, OMNITROPE®)

EFFECTIVE DATE: May 1, 2015

DOCUMENT HISTORY
Original Endorsement Date: 12/13/2004
Subsequent Endorsement Date(s): 11/29/12, 1/30/14; 2/5/15

This policy was developed and approved by the Medica Pharmacy and Therapeutics Committee.

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of somatropin (Humatrope®, Nutropin/Nutropin AQ®, Saizen®, Terv-Tropin®, Serostim®, Zorbtive®, Genotropin®, Norditropin®, Omnitrope®). The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

MEDICAL NECESSITY CRITERIA
I. Indications
   a. Growth hormone deficiency in children and adults
   b. Small for gestational age
   c. Pre-transplant chronic kidney disease
   d. Turner Syndrome
   e. Noonan syndrome
   f. Prader-Willi Syndrome
   g. Cachexia associated with AIDS
   h. Short bowel syndrome (Zorbtive only)

II. Written documentation from the medical record must include:
   a. Diagnosis
   b. Patient age
   c. Prescription written by or recommended by an endocrinologist or nephrologist (except for use in HIV-related wasting)
d. AIDS-related cachexia/wasting syndrome

   Initial therapy
   i. Percent weight loss and time period lost, or the percentage of total body weight composed of BCM (body cell mass) and BMI (body mass index).
   ii. Documentation that patient is taking HIV antiviral therapy
   iii. Documentation that patient has tried dronabinol, oxandrolone, or megestrol

   Renewal
   iv. Documentation that patient has experienced at least 0.5kg/month weight gain while on growth hormone therapy

e. Pediatric growth hormone deficiency

   Initial Therapy
   i. Documentation of non-closure of epiphyseal plate (wrist and hand radiograph)
   ii. Documentation of growth hormone stimulation test, and most recent IGF-1 or IGFBG-3 levels
   iii. Description of patient’s position on a standard growth chart compared to children of the same age and gender

   Renewal
   i. Documentation that patient has shown a positive response to initial growth hormone therapy as evidenced by increases in height or growth velocity, or IGF-1 normalization
   ii. Continued documentation of non-closure of epiphyseal plate (wrist and hand radiograph)

f. Turner’s syndrome, SHOX mutation, Prader-Willi syndrome, or Noonan syndrome

   Initial Therapy
   i. Documentation of diagnosis
   ii. Documentation of non-closure of epiphyseal plate (wrist and hand radiograph)

   Renewal
   iii. Documentation of non-closure of epiphyseal plate (wrist and hand radiograph)

g. Adult growth hormone deficiency

   Initial Therapy
   i. Documentation of cause of growth hormone deficiency
   ii. Documentation of growth hormone deficiency as demonstrated by IGF-1 level or lack of response to a growth hormone stimulation test

   Renewal
   i. Documentation of positive response to GH replacement as evidenced by increase in growth velocity, IGF-1 normalization and/or improvement in body composition.

h. Short Bowel syndrome

   i. Description of specialized nutritional support.

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**COVERAGE ISSUES**

1. Prior authorization is required.
2. Coverage may vary according to the terms of the member’s coverage document.
3. When submitting a request for clinical review, Medica must receive a completed Medication Request Form – Growth Hormone. Complete all fields and fax the form to the MedImpact Prior Authorization Department at 1-858-790-7100 or call 1-800-788-2949.
4. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s coverage document.
5. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica administrative handbook.

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References: