Request for permission for oral testimony at Idaho Medicaid's P&T Committee meeting on 04-15-2011

Submission # 12

The following request has been:

- ○ Approved
- ☒ Denied

## Gennrich, Jane - Medicaid

**From:** Eide, Tamara J. - Medicaid
**Sent:** Tuesday, March 15, 2011 4:27 PM
**To:** Gennrich, Jane - Medicaid
**Subject:** FW: Committee
**Attachments:** FSD00933 Toviaz 2011 Updated Medicaid Supplement.pdf; GNU00347E_RVPTH Handout_FINAL_120610.pdf

**Tami Eide, Pharm.D., BCPS**
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**From:** Heineman, Susan M [mailto:susan.m.heineman@pfizer.com]
**Sent:** Tuesday, March 15, 2011 4:20 PM
**To:** Eide, Tamara J. - Medicaid
**Subject:** Committee

Hi Tami,

I would like to request time to testify for fesoterodine and growth hormones at the April 15th P&T Committee meeting. Thank you!

Sue Heineman, Pharm.D., BCPS
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Pfizer Global Medical
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Pfizer Endocrine Care

**Genotropin®**
(somatropin [rDNA origin] for injection)

## Approved in six indications

### Pediatric indications

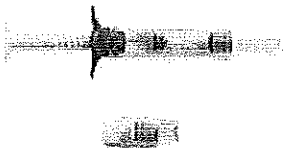
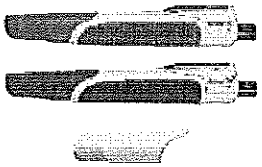
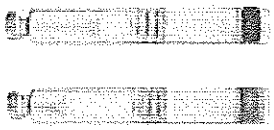
- GENOTROPIN® is indicated for the treatment of growth failure due to the following conditions in **children:**
  - Pediatric growth hormone deficiency (GHD)
  - Small for gestational age (SGA)
  - Idiopathic Short Stature (ISS)*
  - Prader-Willi syndrome (PWS)
  - Turner syndrome (TS)

### Adult indication

- GENOTROPIN is indicated for growth hormone replacement therapy in **adults** with GHD of either childhood- or adult-onset etiology. GHD should be confirmed as appropriate

## GENOTROPIN is indicated for 98% of pediatric patients who require growth hormone therapy†

## Wide range of injection devices to meet patients' needs:

| Genotropin MiniQuick* Growth Hormone Delivery Device containing Genotropin lyophilized Powder (somatropin [rDNA origin] for injection) | Genotropin Pen® Growth Hormone Delivery Device for Use With Genotropin lyophilized Powder (somatropin [rDNA origin] for injection) | Genotropin Mixer® Growth Hormone Reconstitution Device | GENOTROPIN Cartridges§ |
|---|---|---|---|
| The only single use disposable device<br>— No refrigeration required‡<br>— Preservative-free | Flexible incremental dosing, internal reconstitution | Standard syringe system | An overfill of growth hormone to ensure there is enough for the proper dose, even if some is lost inadvertently |
|  <br>Needle guard |  <br>Needle guard | |  |

## Comprehensive patient support: Pfizer Bridge Program®

- Dedicated, personalized support for patients and families
- **One-on-one, in-home** device training and retraining
- 24/7 device support

Pfizer BRIDGEPROGRAM®

* Indicated for the treatment of idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤−2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.

† October 2008-September 2009 patient transaction counts and percentages by diagnosis (based upon 48,987 total pediatric prescriptions for which diagnosis was available). Wolters Kluwer Health Diagnosis Data.

‡ Before reconstitution, MiniQuick can be stored without refrigeration at room temperature (77°F or less) for up to 3 months.

§ Cartridges are used with the GENOTROPIN Pen 5, Pen 12, and Mixer.

***Please see full prescribing information and full Instructions for Use in pocket.***

## Indications

Indicated for the treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (GH).

Indicated for the treatment of pediatric patients who have growth failure due to Prader-Willi syndrome (PWS).The diagnosis of PWS should be confirmed by appropriate genetic testing (see CONTRAINDICATIONS).

Indicated for the treatment of growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2.

Indicated for the treatment of growth failure associated with Turner syndrome (TS).

Indicated for the treatment of idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤–2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.

Indicated for growth hormone replacement therapy in adults with growth hormone deficiency (GHD) of either childhood- or adult-onset etiology. GHD should be confirmed as appropriate.

## Important Safety Information

Somatropin should not be used for growth promotion in pediatric patients with closed epiphyses.

Somatropin is contraindicated in patients with active proliferative or severe nonproliferative diabetic retinopathy. Somatropin is contraindicated in patients with active malignancy. Because growth hormone deficiency may be a sign of pituitary or other brain tumors, the presence of such tumors should be ruled out before treatment is initiated. Somatropin should not be used in patients with any evidence of progression or recurrence of an underlying intracranial tumor.

Somatropin should not be used to treat patients with acute critical illness due to complications from surgery, trauma, or respiratory failure; the safety of continuing somatropin treatment for approved uses in patients who develop these illnesses has not been established.

Somatropin is contraindicated in patients with Prader-Willi syndrome who are severely obese or have respiratory impairment (see WARNINGS).

Monitor patients with glucose intolerance closely; dosage of antihyperglycemic drug may need to be adjusted. Monitor carefully if somatropin is administered in combination with glucocorticoid therapy and/or other drugs metabolized by the CP450 pathway.

In childhood cancer survivors, an increased risk of a second neoplasm, in particular meningiomas, has been reported in patients treated with somatropin after their first neoplasm, particularly those who were treated with cranial radiation.

Slipped capital femoral epiphyses may occur more frequently in patients with endocrine disorders or in patients undergoing rapid growth.

Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk.

The cartridges of GENOTROPIN® contain m-Cresol and should not be used by patients with a known sensitivity to this preservative.

Subcutaneous injection of somatropin at the same site repeatedly may result in tissue atrophy. This can be avoided by rotating the injection site.

A health care provider should supervise the first injection and provide appropriate training and instruction for the proper use of all devices for GENOTROPIN.

Rx only.

**Genotropin®**

*(somatropin [rDNA origin] for injection)*

***Please see full prescribing information and full Instructions for Use in pocket.***

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