BlueCross BlueShield Nebraska

VOXZOGO (REQUIRES PREAUTHORIZATION)

X.190

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POLICY

TARGET AGENT(S)

Voxzogo (vosoritide) is FDA approved:

- To increase linear growth in pediatrics patients with achondroplasia are 5 years of age and older with open epiphyses.[1]

Brand (generic)	GPI (NDC)	Multisource Code	Quantity Limit (per day or as listed)
Voxzogo (vosoritide)			
0.4mg vial for injection	30950080002120	M, N, O, or Y	1 vial
0.56mg vial for injection	30950080002130	M, N, O, or Y	1 vial
1.2mg vial for injection	30950080002140	M, N, O, or Y	1 vial

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

I. Target Agent(s) may be considered medically necessary when **ALL** of the following are met:

A. **ONE** of the following:

1. The requested agent is eligible for continuation of therapy **AND ONE** of the following:

OR

b. The prescriber states the patient has been treated with the requested agent within the past 90 days **AND** is at risk if therapy is changed

OR

2. The patient has a diagnosis of achondroplasia as confirmed by genetic testing

AND

3. The requested agent will be used to increase linear bone growth

AND

4. The patient has open epiphyses

AND

5. The patient is ambulatory and able to stand without assistance

AND

B. **ONE** of the following:

1. The patient's age is within FDA labeling for the requested indication for the request agent

OR

2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication

AND

C. The prescriber is a specialist in the area of the patient's diagnosis: (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

AND

D. The patient will **NOT** be using the requested agent in combination with another growth hormone agent for the requested indication

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the requested agent

AND

F. **ONE** of the following:

1. The requested quantity (dose) does **NOT** exceed the program quantity limit

OR

2. **ALL** of the following:

a. The requested quantity (dose) is greater than the program quantity limit

AND

b. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication

AND

c. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

3. **ALL** of the following:

a. The requested quantity (dose) is greater than the program quantity limit

AND

b. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

AND

c. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

I. Target agent(s) will be approved when **ALL** of the following are met:

A. The patient has been previously approved for the requested agent through the plans Prior Authorization process

AND

B. The patient has had clinical benefit with the requested agent

AND

C. The patient has open epiphyses

AND

D. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of patient's diagnosis

AND

E. The patient will **NOT** be using the requested agent in combination with another growth hormone agent for the requested indication

AND

F. The patient does **NOT** have any FDA labeled contraindications to the requested agent

AND

G. **ONE** of the following:

1. The requested quantity (dose) does not exceed the program quantity limit

OR

2. **ALL** of the following:

a. The requested quantity (dose) is greater than the program quantity limit

AND

b. The requested quantity (does) does not exceed the maximum FDA labeled dose for the requested indication

AND

OR

3. **ALL** of the following:

   a. The requested quantity (dose) is greater than the program quantity limit

   AND

   b. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication

   AND

   c. Information has been provided in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

Dates

Original Effective
02-16-2022
Last Review
11-06-2024
Next Review
11-09-2025

BACKGROUND

Achondroplasia

Achondroplasia is the most commonly occurring abnormality of bone growth (skeletal dysplasia), occurring in approximately 1 in 15,000-35,000 live births and affects both males and females equally. This genetic disorder is caused by a mutation in the fibroblast growth factor receptor 3 (FGFR3) gene. Fibroblast growth factor receptors (FGFRs) belong to the tyrosine kinase family and regulate various biological processes including cell proliferation and differentiation during development, as well as tissue repair.

the abnormal gene from an affected parent to an offspring is 50% for each pregnancy.[3] Like some other severe growth disorders, it is also associated with potentially serious medical complications such as foramen magnum and spinal stenosis, both of which cause increased morbidity and mortality.[2] This genetic disorder is characterized by an unusually large head (macrocephaly), short upper arms (rhizomelic dwarfism), and short stature (adult height of approximately 4 feet). Achondroplasia does not typically cause impairment or deficiencies in mental abilities. If the bones that join the head and neck do not compress the brainstem or upper spinal cord (craniocervical junction compression), life expectancy is near normal.[3]

Growth hormone treatment has been found to be ineffective in patients with deformities of the lower limbs and to date, it has not been confirmed whether the administration of somatropin negatively affects the severity of foramen narrowing and pressure on the spinal cord, and no symptoms of acromegaly have been observed in the treated patients. A meta-analysis of recombinant human growth hormone treatment in achondroplasia based on an extensive group of patients shows that data about body disproportion in GH treatment are ambiguous.[5]

Efficacy

Voxzogo, a recombinant C-type natriuretic peptide analog that stimulates endochondral ossification, a process that is inhibited in patients with achondroplasia patients.

The safety and effectiveness of Voxzogo in 121 genetically confirmed patients with achondroplasia were assessed in one 52-week, multi-center, randomized, double-blind, placebo-controlled, phase 3 study - Study 1 (NCT03197766). The dosage of Voxzogo was 15 mcg/kg administered subcutaneously once daily. Baseline standing height, weight Z-score, body mass index (BMI) Z-score, and upper to lower body ratio were collected for at least 6 months prior to randomization. Subjects with limb-lengthening surgery in the prior 18 months or who planned to have limb-lengthening surgery during the study period were excluded and patients must have been ambulatory and able to stand to participate.[6] The study included a 52-week placebo-controlled treatment phase followed by an open-label treatment extension study period in which all subjects received Voxzogo. The primary efficacy endpoint was the change from baseline in annualized growth velocity (AGV) at Week 52 compared with placebo. The subjects' ages ranged from 5.1 to 14.9 years with a mean of 8.7 years. Sixty four (53%) subjects were male and 57 (47%) were female. Overall, 86 (71%) subjects were White, 23 (19%) were Asian, 5 (4%) were Black or African American, and 7 (6%) were classified as "multiple" race. The subjects had a mean baseline height standard deviation score (SDS) of -5.13. Patients treated with vosoritide had a greater increase in mean annualized growth velocity from baseline to 52 weeks compared with the placebo group (adjusted mean difference 1.57 cm/year; 95% CI 1.22-1.93).

Longer-term studies are needed to determine whether vosoritide effects pubertal growth velocity, body segment proportionality, final adult height, or complications associated with achondroplasia.

Safety[1]

Voxzogo does not have any contraindications.

REFERENCES

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Högler, W., Ward, LM New developments in the management of achondroplasia. Wien Med Wochenschr 170, 104–111 (2020). https://doi.org/10.1007/s10354-020-00741-6.

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REVISIONS

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