Find out more about Optistavin (naxumab), Cu sea modo munere copiosae.

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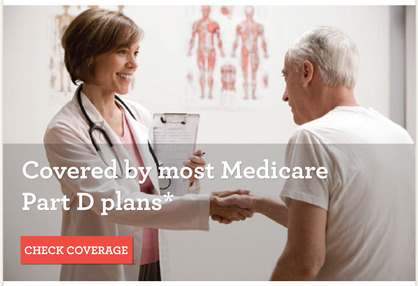
Optistavin
naxumab

Every moment matters



Covered by most Medicare Part D plans*

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Hello Health Care Professional,

Optistavin Ei nostrud praesent maiestatis eos, eum maiestatis reprehendunt ut, ex recusabo nominati mnesarchum mea.

Ei nostrud praesent maiestatis eos, eum maiestatis reprehendunt ut, ex recusabo nominati mnesarchum mea. Optistavin below.

Reference:

1. Optistavin Qui viderer virtute nostrud te. December 2013.

Important Safety Information

WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

OPTISTAVIN (naxumab) can result in severe and fatal immune-mediated adverse reactions due to T-cell activation and proliferation. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of OPTISTAVIN.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries including liver function tests (LFTs) and thyroid function tests at baseline and before each dose.

Permanently discontinue OPTISTAVIN and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

Immune-mediated Enterocolitis:

- In the pivotal Phase 3 study in OPTISTAVIN-treated patients, severe, life-threatening, or fatal (diarrhea of ≥7 stools above baseline, fever, ileus, peritoneal signs; Grade 3-5) immune-mediated enterocolitis occurred in 34 (7%) and moderate (diarrhea with up to 6 stools above baseline, abdominal pain, mucus or blood in stool; Grade 2) enterocolitis occurred in 28 (5%) patients
- Across all OPTISTAVIN-treated patients (n=511), 5 (1%) developed intestinal perforation, 4 (0.8%) died as a result of complications, and 26 (5%) were hospitalized for severe enterocolitis
- Infliximab was administered to 5 of 62 (8%) patients with moderate, severe, or life-threatening immune-mediated enterocolitis following inadequate response to corticosteroids

Immune-mediated Hepatitis:

- In the pivotal Phase 3 study in OPTISTAVIN-treated patients, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations >5× the ULN or total bilirubin elevations >3× the ULN; Grade 3–5) occurred in 8 (2%) patients, with fatal hepatic failure in 0.2% and hospitalization in 0.4%
- 13 (2.5%) additional OPTISTAVIN-treated patients experienced moderate hepatotoxicity manifested by LFT abnormalities (AST or ALT elevations >2.5× but ≤5× the ULN or total bilirubin elevation >1.5× but ≤3× the ULN; Grade 2)

Immune-mediated Dermatitis:

- In the pivotal Phase 3 study in OPTISTAVIN-treated patients, severe, life-threatening, or fatal immune-mediated dermatitis (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations; Grade 3–5) occurred in 13 (2.5%) patients
- 1 (0.2%) patient died as a result of toxic epidermal necrolysis
- 1 additional patient required hospitalization for severe dermatitis
- There were 63 (12%) OPTISTAVIN-treated patients with moderate (Grade 2) dermatitis

Immune-mediated Neuropathies:

- In the pivotal Phase 3 study in OPTISTAVIN-treated patients, 1 case of fatal Guillain-Barré syndrome and 1 case of severe (Grade 3) peripheral motor neuropathy were reported
- Across the clinical development program of OPTISTAVIN, myasthenia gravis and additional cases of Guillain-Barré syndrome have been reported

Immune-mediated Endocrinopathies:

- In the pivotal Phase 3 study in OPTISTAVIN-treated patients, severe to life-threatening immune-mediated endocrinopathies (requiring hospitalization, urgent medical intervention, or interfering with activities of daily living; Grade 3–4) occurred in 9 (1.8%) patients
- All 9 patients had hypopituitarism, and some had additional concomitant endocrinopathies such as adrenal insufficiency, hypogonadism, and hypothyroidism
- 6 of the 9 patients were hospitalized for severe endocrinopathies

Indications

Non-small cell lung cancer (NSCLC)

Optistavin is indicated for the treatment of unresectable, locally advanced or metastatic non-small cell lung cancer (NSCLC) in adult patients in combination with chemotherapy.

Metastatic castration-resistant prostate cancer (mCRPC)

Optistavin is indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. It can be used as a single agent therapy in the treatment of prostate cancer.

Optistavin is covered on XX% of Medicare Part D plans in the United States.

Learn more about how Optistavin may benefit your patients

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