Utilization of Romiplostim in Myelodysplastic Syndromes (MDS) within the Medicare Population: A Study Based on Data from the Surveillance, Epidemiology, and End Results (SEER)-Medicare Linked Database – Original Analysis & Follow-up Analysis (20190354, 20150177)

First published: 09/11/2019

Last updated: 05/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS31161

Study ID

32548

DARWIN EU® study

No

Study countries

United States

Study description

Nplate® (romiplostim) is not indicated for treatment of thrombocytopenia due to myelodysplastic syndromes (MDS) or any other cause of thrombocytopenia other than chronic ITP. On 25 June 2014, Amgen received an Information Request from the Food and Drug Administration (FDA) to examine off-label use of romiplostim with a particular interest in use among patients who have MDS. Through discussions between Amgen and the FDA, it was agreed upon that the Surveillance, Epidemiology, and End Results (SEER)-Medicare linked database would be an appropriate source of data to examine this question. Amgen conducted these analyses and submitted the report to the Agency on 20 November 2015. On 27 April 2018, the Agency requested that Amgen re-run the analysis based on the most recent release of SEER-Medicare data. The current report reflects results of both the original and updated analyses, which are referred to as the Original Analysis and Follow-up Analysis, respectively, throughout the report.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/11/2018

Study start date

Actual: 20/03/2019

Data analysis start date

Actual: 20/03/2019

Date of final study report
Actual: 26/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To estimate the proportion of all romiplostim users who have a diagnosis of MDS registered in SEER.To estimate the proportion of SEER-registered MDS patients who are romiplostim users.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

NPLATE

Medical condition to be studied

Myelodysplastic syndrome

Population studied

Short description of the study population

Patients aged ≥65 years at cancer diagnosis for the SEER sample and in the year of analysis for the 5% non-Myelodysplastic Syndromes (MDS) sample; had continuous Medicare Part A and Part B coverage during the time periods of the analysis; and had no Health Maintenance Organization benefits.
In the Original Analysis, patients diagnosed with MDS in any year from 2001 to 2011 were included in the MDS cohort; and patients with no diagnosis of MDS in any year (through 2011) were included in the non-MDS cohort. For the Follow-up Analysis, patients diagnosed with MDS in any year from 2005 to 2015 were included in the MDS cohort; and patients with no diagnosis of MDS in any year (through 2015) were included in the non-MDS cohort.

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Myelodysplastic Syndromes patients

Estimated number of subjects

415000

Study design details

Outcomes

1) romiplostim users with a diagnosis of MDS, 2) romiplostim use among MDS patients

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Data analysis plan

Each cohort of romiplostim users (non-MDS and MDS, by year of romiplostim initiation) was described by baseline measures, including age at romiplostim initiation (median and interquartile range IQR), sex, race (White/Other), and year of romiplostim initiation. The median (IQR) number of romiplostim administrations per person-year, history of ITP prior to romiplostim use, history of other thrombocytopenia prior to romiplostim use, and median (IQR) time between MDS diagnosis and first romiplostim administration in days were also described for each cohort.MDS patients who did and did not have romiplostim use were described by age at diagnosis (median IQR), sex, race (White/Other), and time period of diagnosis. Chemotherapy use within 180 days after MDS diagnosis, chemotherapy use prior to or within 30 days after romiplostim use, leukemia diagnosed after MDS, leukemia diagnosed before MDS, thrombocytopenia before MDS, and ITP before MDS were described.

Documents

Study results

20150177 (20190354)_Romiplostim use in MDS_UPDATE_Final_Abstract June 2019.pdf(66.98 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No