International Differences in the Use of Mepolizumab to Treat Severe Asthma – Impact of Reimbursement Policies

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Background & Aims

SEA is a phenotype of severe asthma characterized by persistent eosinophilic inflammation, leading to more frequent exacerbations.[1]

The anti-IL-5 humanized monoclonal antibody mepolizumab inhibits IL-5 signaling and blocks eosinophil survival and proliferation.[2,3] Mepolizumab is an approved add-on biologic treatment for SEA and is licensed in multiple countries worldwide.[4,5]

The reimbursement criteria to cover payment of mepolizumab vary by country. Key criteria include BEC and history of asthma exacerbations.

The REALITI-A study is a multinational, real-world cohort study, which recruited patients with SEA who were newly prescribed mepolizumab in order to assess the real-world clinical outcomes in these patients.

Here we aim to characterize the difference in demographic and clinical characteristics of the patients initiating mepolizumab treatment in real-life settings by country and to evaluate the impact of national HTA policies on the use of mepolizumab.

Methods

REALITI-A (GSK ID: 204710)
Study Design

- Real-world
- Observational
- Prospective
- Global
- Single-arm

Clinical diagnosis of asthma:
≥18 years of age
Newly prescribed mepolizumab
Relevant medical records available
≥12 months data prior to enrollment

Standard-of-care therapy, plus:
Mepolizumab 100 mg SC*
At physician's discretion

Study enrollment period: **Dec 2016 to Oct 2019**
24-month follow-up period
822 patients treated *from* 84 centers in **7 countries**†

Baseline clinical characteristics at initiation of mepolizumab were assessed by country:
Mean # exacerbations‡ | Geo. Mean BEC cells/µl§ | mOCS % use¶ | Mean asthma duration | Mean ACQ-5 score** | Geo. Mean total IgE**

Belgium, Canada, Germany, Italy, Spain, UK, Scotland††, USA

*Patients initiating mepolizumab at a dose differing from the approved dose of 100 mg SC have been excluded from this analysis; †UK including England, Scotland, Wales and Northern Ireland; ‡in the 12 months prior to initiation; §at time of initiation (in the 90 days prior to initiation) and highest in the 12 months prior to initiation; ¶During the period including the initiation date and 27 days prior; **reported in the 90 days prior to treatment initiation; ††Scotland has different reimbursement criteria to the rest of the UK and was therefore analyzed separately; data from Scotland are also included in the UK data.

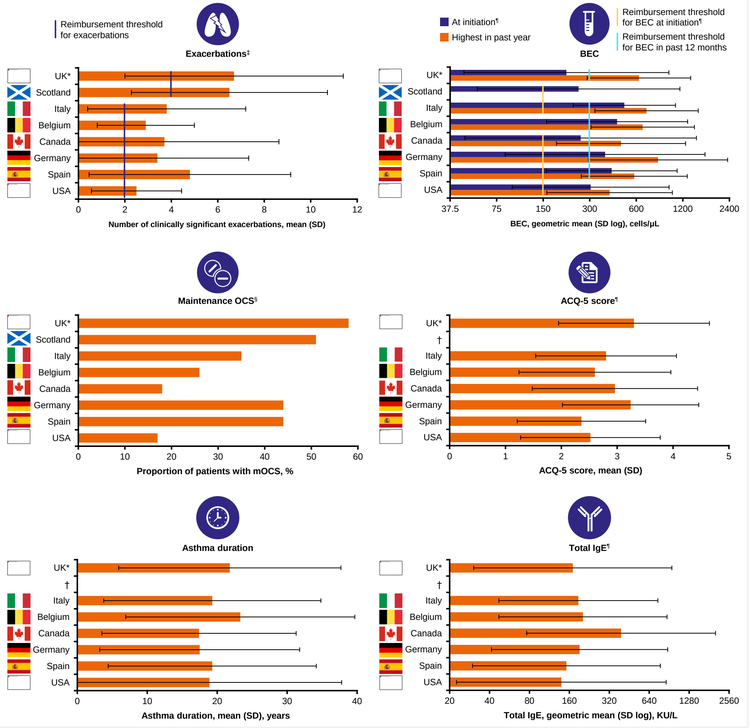
Results

Main reimbursement criteria for blood eosinophil count AND exacerbations recommended by national HTA agency

Country	Number of patients	Minimum BEC, cells/µL: ≥150 at treatment initiation	Minimum BEC, cells/µL: OR vs AND	Minimum BEC, cells/µL: ≥300 in the past 12 months	Minimum number of exacerbations in the past 12 months
UK (England, Wales and Northern Ireland)	200 (126)*			✓	4
UK (Scotland)	74	✓			4
Italy	244	✓	AND	✓	2
Belgium	42			✓	2
Canada†	57	✓ ‡	OR	✓	2
Germany†	85	✓	OR	✓	2
Spain†	94	✓	OR	✓	2
USA§	100	✓ ¶			2 **

*Excluding Scotland; †BEC and exacerbation criteria are consistent with RCT inclusion criteria; ‡BEC ≥150 cells/µL and are receiving mOCS; §in the USA criteria vary by individual health plan. Details shown are representative of United Healthcare®; ¶BEC ≥150 cells/µL or are receiving mOCS®; **each exacerbation defined as a burst of SCS for at least 3 days. This is one of a number of alternative criteria used to demonstrate lack of asthma control, which also include ACQ score consistently >1.5, asthma related emergency treatment, FEV_1 score <80% predicted, or dependence on mOCS®.

Patient clinical characteristics at study baseline by country (ordered from most to least restrictive reimbursement criteria for BEC and exacerbations)



*UK data includes data for Scotland; †data not available for Scotland. ‡In the 12 months prior to initiation; §during the period including the initiation date and 27 days prior; ¶in the 90 days prior to initiation.

Conclusions

- This real-world study demonstrates that the clinical characteristics of patients at mepolizumab initiation differ and are influenced by the reimbursement criteria of the country.
- In countries with more restrictive policies, such as the UK, markers of more severe disease, such as the mean number of clinically significant exacerbations in the prior year, the proportion of patients with mOCS use, and mean ACQ-5 scores, are higher than those with less restrictive policies.
- In the USA, where reimbursement policies vary by individual health plan, patients had the lowest mean number of exacerbations in the year prior to initiation and fewer patients used mOCS compared with other countries.
- Funding policies for mepolizumab reimbursement appear to influence the initiation and use of mepolizumab. Patients in more restrictive markets may be denied potential improvement in the well-being and health-related quality of life shown by patients in less restrictive markets.
- Understanding the potential impact of reimbursement policies on clinical outcomes and consequent OCS burden is necessary to better inform healthcare policymakers.

Abbreviations

ACQ-5, asthma control questionnaire-5; BEC, blood eosinophil count; FEV_1, forced expiratory volume 1 second; HTA, health technology assessment; IgE, immunoglobin E; IL, interleukin; mOCS, maintenance oral corticosteroid; RCT, randomized clinical trial; SC, subcutaneous; SD, standard deviation; SEA, severe eosinophilic asthma.

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