INTRODUCTION:

Crohn’s disease (CD) is a long-term condition in which inflammation of the digestive system leads to diarrhea, abdominal pain, fatigue, and weight loss. There are no cures for CD at the moment (1).

When CD is in active, drug treatment is usually aimed to manage the symptoms quickly and to bring remission.

Prevalence of CD for Germany in 2010 was 322 (95% confidence interval [CI]: 302–346) per 100,000, or there will be 91,100 cases in the number suggesting for CD prevalence in Germany since the 1980s, which need to be adapted by healthcare services and dealt with the burden associated with increasing numbers of patients (2).

New therapies have been launched in Europe over the last few years. One key question remains: how many new therapies can patients get in terms of market access in various European countries and have the national HTA agencies have different views?

This study visualizes the heterogeneous multiple decision by EU-5 HTA agencies using the Prismaccess/ENTYVIO database and their three colored scale. Hence, this study will shed light on these decisions in a transparent and understandable manner for industry.

METHODS:

The international HTA database Prismaccess® includes over 20,000 decisions by market access authorities worldwide.

This study includes the decisions of the following authorities (countries):

- France – Transparency Committee Haute Autorité de Santé – TC HAS / CEESP
- Germany – Federal Joint Committee – G-BA
- Italy – Decisions on regional level of the Regions Emilia-Romagna & Veneto. Additionally, on a national level decisions of Patients’ Association – ANP are considered. Going on, in Spain – Agency Española de Medicamentos y Productos Sanitarios – AEMPS; additionally, decisions on the level of the Hospital Network (GENESIS) and also regional decisions of Andalucia, Aragon, Balear, Cantabria (CAMPA) were considered.
- Scotland – Scottish Medicines Consortium – SMC
- UK – National & Regional authorities (Adalinumab, Infliximab, Vedolizumab).

The delay in action of ENTYVIO, during which patients remain exposed to frequent adverse effects.

The Pharmacotherapeutic Harmonization Program recommends the use of anti-TNFα inhibitors for patients who have had an inadequate response with, lost response to, or were intolerant to a TNF-antagonist or have medical contraindications to use biological therapies.

RESULTS:

A total of 50 decisions have been considered for the five countries since January 2011 until October 2018 for 10 different drugs. Figure 1 shows the development over time. The number of decisions per month in the presented graph distinguishes between Adalinumab, Infliximab, Vedolizumab, as also new biologics.

The most decisions are identified for the French HTA (25 assessments). The high number is explained as well as a number of new drugs that were already approved. The data were triangulated with Adalinumab, Infliximab, Vedolizumab, as also new biologics.

For Scotland, 12 of 12 decisions were identified by SMC. As in France, multiple decisions for one drug are waiting for a further decision. In total, Adalinumab (2), Infliximab (2), Stulbun (2) and Vedolizumab (2) were assessed.

For the other countries such as England, Germany and Spain, only decisions for Ustekinumab and Vedolizumab could be identified. In detail for Germany – G-BA (1) (Ustekinumab), England – NICE (1) (Ustekinumab), (Vedolizumab), and Spain – 5 national and regional (Adalinumab, Infliximab, Vedolizumab) were assessed.

For the UK, additional cost-effectiveness decisions from the CESR for Ustekinumab and upcoming anti-TNF therapy have been made.

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CONCLUSIONS:

- Evidence requirements substantially differ by HTA agency of EU-5 countries and this needs to be considered by industry for both their local HTA submissions and global lifecycle planning/strategy. Knowledge of this heterogeneity is crucial for industry to reach that large target across EU-5 countries.

- As shown with the examples of Vedolizumab and Ustekinumab, decision for reimbursement differ in the range of global benefit and also in terms of the patient population, in which the drug is reimbursed or not reimbursed. Also differences can be seen for the appropriate comparator therapies, especially for the use of placebo which is accepted in some countries.

- The authors underline that one centralized HTA process does not make sense due to several and multiple singularities of such market such as the different definition of standard of care.

- The visualization of the heterogeneous multiple decision by EU-5 HTA agencies using the Prismaccess/ENTYVIO database and their three colored scale makes this heterogeneity more transparent and understandable for industry.

Table 1: National grading systems and overall grading system in the Prismaccess®/ENTYVIO database

Table 2: Results for Vedolizumab (ENTYVIO) in the Prismaccess®/ENTYVIO database

Table 3: Results for Ustekinumab (STELARA) in the Prismaccess®/ENTYVIO database

REFERENCES: