Recommendation No. 143/2021
of 23 December 2021
of the President of the Agency for Health Technology Assessment and Tariff System
on the assessment of Entyvio (vedolizumab) under the drug programme:
"Treatment of ulcerative colitis (UC) (ICD-10 K51)"

The President of the Agency does not recommend the reimbursement of Entyvio (vedolizumab) under the drug programme "Treatment of ulcerative colitis (UC) (ICD-10 K51)".

The President of the Agency recommends the reimbursement of Entyvio (vedolizumab) under the currently funded drug programme "Treatment of patients with ulcerative colitis (UC) (ICD-10 K51)" provided that the cost of treatment with vedolizumab administered subcutaneously does not exceed the cost of treatment with the cheapest biopharmaceutical currently reimbursed for the treatment of UC.

Grounds for the recommendation

This assessment concerns Entyvio (vedolizumab) for subcutaneous administration. Similarly to the previously assessed one, which concerned the intravenous form of vedolizumab (Recommendation No. 78/2020), the analysed application also concerns the removal of the time limit for vedolizumab therapy, the consideration in the inclusion criteria of the drug programme also a moderate form of the disease and a change in the current inclusion criterion according to the Mayo scale from > 6 points to ≥6 points. Proposed changes to the programme were positively evaluated in the above-mentioned recommendation provided that the appropriateness of vedolizumab treatment continuation is assessed at least once every 12 months and the costs of therapy are reduced.

The systematic review does not provide evidence in the form of clinical studies directly comparing vedolizumab administered subcutaneously (VED s.c.) with vedolizumab administered intravenously (VED i.v.). However, the clinical analysis, based on an indirect comparison, showed no significant differences in the efficacy and safety of the evaluated drug compared to the comparator.

The choice of the comparator is not questioned. This will probably be the most commonly substituted therapy. However, it cannot be excluded that in practice, other intravenous therapies will also be replaced by vedolizumab administered subcutaneously.

However, given that there are no reasons to conclude that there are differences in the efficacy of subcutaneous vs intravenous therapy, the economic evaluation was performed using cost-minimisation analysis. The use of vedolizumab administered subcutaneously [information protected as a trade secret] in maintenance therapy was estimated to lead to UC compared to the use of vedolizumab administered intravenously, [information protected as a trade secret]

The lack of efficacy difference does not justify funding the subcutaneous therapy at a price [information protected as a trade secret]
than the intravenous therapy.

If the subcutaneous therapy was only to replace the intravenous therapy (without differences in other cost categories), [information protected as a trade secret] should be expected, which is not justified due to the lack of differences in health outcomes. Considering the possibility of replacing infliximab or tofacitinib therapy with vedolizumab therapy, the cost of therapy with vedolizumab administered subcutaneously should be reduced to the cost of the cheapest therapy used in the programme (as suggested in other recommendations such as the CADTH recommendation).

According to the guidelines, TNF inhibitors and vedolizumab are recommended for patients with a moderate to severe form of the disease for whom standard treatment has proved to be ineffective or inapplicable. However, the guidelines did not indicate the appropriate, recommended or preferred route of vedolizumab administration.

Vedolizumab administered subcutaneously is to be used in maintenance treatment so the proposed risk-sharing scheme conditions for [information protected as a trade secret]

Considering the conclusions drawn from the clinical and economic analysis, funding therapy with vedolizumab administered subcutaneously is justified only if the cost of treatment does not exceed the cost of treatment with the cheapest biopharmaceutical currently reimbursed in UC treatment.

Subject of the application

The order of the Minister of Health concerns the assessment of the appropriateness of public reimbursement of the following medicinal product:

- Entyvio, vedolizumab, solution for injection, 108 mg, 2, injection, EAN code: 07038319122857, proposed net sales price: [information protected as a trade secret]

Proposed payment and dispensing category: free of charge, the drug is to be used under the drug programme as part of the already existing limit group: 1176.0, Vedolizumab.

The applicant has proposed a risk-sharing scheme.

Health problem

Ulcerative colitis (UC, ICD-10 K52 code) is a diffuse non-specific inflammatory process of the rectum or rectum and colon mucosa that leads in some cases to ulceration. In ulcerative colitis, lesions most often begin in the rectum and sigmoid colon, from where they spread continuously and, in advanced cases, occupy the entire large intestine.

Together with Crohn's disease, ulcerative colitis belongs to a group of non-specific inflammatory bowel diseases of unknown aetiology. The aetiopathogenesis of these diseases includes genetic, environmental and immunological factors.

Most UC cases occur between the age of 20 and 40, with about 15-20% of cases starting in school-aged children and adolescents. The incidence in Europe in the general population is 10/100,000 inhabitants/year, while in the United States, it is 8.8/100,000 inhabitants/year. There are no clear data defining the size of the population of patients with ulcerative colitis in Poland. Based on data of the Institute of Healthcare Management (IZWOZ) from 2017, the number of patients can be

estimated at approximately 35-40,000.

British epidemiological data published by the NICE reveal that approximately 80% of those affected suffer from a mild or moderate form of the disease, while 20% of patients have severe UC. Within 10 years of the disease, 20% of adults require a colectomy.

In patients with ulcerative colitis, periods of spontaneous regression of symptoms, the so-called "remission", are a general rule. Still, after a few weeks, months or even years, the disease symptoms may recur. There is also a group of patients who experience permanent symptoms of various intensity. In around 5% of cases, the course of the disease is life-threatening.

During the chronic course of ulcerative colitis, there are acute and recurrent flare-ups. In most cases, ulcerative colitis causes the catarrh of colitis with bloody diarrhoea, hypoproteinaemia, anaemia and weight loss. Untreated ulcerative colitis can lead to fistula, perianal abscess, bowel stenosis or perforation into the peritoneal cavity as well as to severe anaemia. Deep ulceration of the colonic mucosa can cause life-threatening complications such as colon perforation and toxic colon distension, as well as complications such as hepatitis, cholangitis and peritonitis.

Alternative health technology

Considering the technologies currently reimbursed, therapy with vedolizumab administered intravenously was considered as a comparator for the applied technology.

The comparator choice is not questioned. This will probably be substituted therapy. However, it cannot be excluded that in practice, eventually, other intravenous therapies will also be replaced by vedolizumab administered subcutaneously.

Description of the proposed intervention

Vedolizumab is a monoclonal antibody that binds specifically to the α4β7 integrin, which is preferentially expressed on gut homing T helper lymphocytes. By binding to α4β7 on certain lymphocytes, vedolizumab inhibits adhesion of these cells to mucosal addressin cell adhesion molecule-1 (MAdCAM-1), but not to vascular cell adhesion molecule-1 (VCAM-1). MAdCAM-1 is mainly expressed on gut endothelial cells and plays a critical role in the homing of T lymphocytes to tissues within the gastrointestinal tract.

According to Summary of Product Characteristics (SmPC), Entyvio is recommended for the treatment of adult patients with:

- moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.
- moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.

The SmPC for Entyvio does not specify the duration of therapy.

The indication specified in the application is included in the registration indication.

The drug in the intravenous form is currently funded (based on the Announcement of the Ministry of Health of 21 October 2021) under the B.55 drug programme "Treatment of patients with ulcerative colitis (UC) (ICD-10 K51)".

In addition to the introduction of a subcutaneous form of vedolizumab, this reimbursement application requests for changes to the current eligibility condition according to the Mayo Scale – from >6 points. to ≥6 points and to remove the time limit for vedolizumab therapy, leaving the total duration of the treatment in the programme to doctors to decide.

The changes proposed by the applicant in this reimbursement application have already been assessed in a previous application related to the reimbursement of Entyvio for intravenous

administration under the drug programme for the treatment of ulcerative colitis. The recommendation was positive for adding changes from the reimbursement application to the B.55 drug programme funded at that time provided that the programme provisions included the need to assess the appropriateness of continuing treatment with vedolizumab at least once every 12 months, which was included in the proposed draft of the drug programme.

According to the current Announcement of the Ministry of Health of 21 October 2021, the existing B.55 drug programme in the treatment of ulcerative colitis did not consider the proposed changes recommended by the Agency for Health Technology Assessment and Tariff System; however, information was received about an ongoing separate process of reducing the time limit for vedolizumab therapy in the B.55 drug programme.

Moreover, the proposed name of the drug programme, i.e. "Treatment of ulcerative colitis (UC) (ICD-10 K51)", is not the same as the name of the current drug programme, which is "Treatment of patients with ulcerative colitis (UC) (ICD-10 K51)".

Efficacy, effectiveness and safety assessment

This assessment involves collecting data on the health consequences (efficacy and safety) of the new therapy for the health problem in question and of other therapies that are currently reimbursed from public funds and represent alternative therapies available for the health problem. Furthermore, this assessment requires determination of the reliability of data collected and a comparison of the efficacy and safety results of the new therapy against the therapies already available to treat the health problem in question.

On the basis of the above, the efficacy and safety assessment allows answering the question of the scale of the health outcome (both in terms of efficacy and safety) to be expected from the new therapy compared with other therapeutic options under consideration.

No clinical studies directly comparing vedolizumab administered subcutaneously (VED s.c.) with vedolizumab administered intravenously (VED i.v.) were identified.

Three primary studies were included in the systematic review:

- VISIBLE I – randomised, double-blind, phase III study to evaluate the efficacy and safety of VED i.v. (induction), VED s.c. (maintenance therapy) and PLC (publication Sandborn 2020, EMA 2020 document, VISIBLE_protocol, Sandborn 2019 abstract, CADTH 2020 review);
- VISIBLE OLE - single-arm open-label phase IIIb study that extends the VISIBLE I study. (Vermeire 2020 abstract, EMA 2020 document).
- GEMINI I - randomised, double-blind, phase III study comparing the efficacy and safety of VED i.v. compared to PLC (publications Feagan 2013, Feagan 2017a, Feagan 2017b, Sandborn 2019, EMA 2014 document)

The results obtained in the VISIBLE I and GEMINI I studies were compared indirectly.

In addition, 4 systematic reviews were included: Bhandari 2021, Jairath 2021, CADTH 2020 and D'Amico 2020, in which efficacy and safety data for vedolizumab administered subcutaneously were derived from the VISIBLE I study.

In the studies, the following endpoints were mainly assessed:

- Clinical remission
- Clinical response
- Mucosal healing
- Serious adverse events
- Quality of life

The reliability assessment of the VISIBLE I and GEMINI I studies was performed using the Cochrane Collaboration risk-of-bias assessment tool. In each of the analysed domains, the risk of bias was determined to be low.

Efficacy

Direct comparison of VED s.c. vs VED i.v. (VISIBLE I, GEMINI I)

- Quality of life

Statistically significant differences were observed in favour of vedolizumab administered subcutaneously for a change in IBDQ (MD=22.80, 95% CI: [6.61; 38.99]) and EQ-5D-VAS (MD=8.30, 95% CI: [0.16; 16.44]) scores.

When considering the interpretation of the results of the questionnaires, the differences are not clinically significant.

- Clinical remission, sustained response, mucosal healing

There were no statistically significant differences between vedolizumab administered subcutaneously and vedolizumab administered intravenously in terms of: sustained response, mucosal healing and endpoints related to disease remission (clinical remission, sustained clinical remission, clinical remission without the need for corticosteroids).

Indirect comparison of VED s.c. vs PLC (VISIBLE I)

In the subcutaneous vedolizumab group, compared to the placebo group, the following were reported more frequently:

- clinical remission: 46.2% vs 14.3%, RD = 0.323 (95% CI: 0.197; 0.450);
- mucosal healing: 56.6% vs 21.4%, RD = 0.357 (95% CI: 0.221; 0.493);
- sustained response: 64.2% vs 28.6%, RD = 0.361 (95% CI: 0.212; 0.509).

Continuation of VED s.c. treatment - VISIBLE OLE study

In the subgroup of patients continuing therapy with vedolizumab administered subcutaneously, after completion of the VISIBLE I study (the study ended after 52 weeks), the quality of life measured by the IBDQ questionnaire decreased by an average of 8.32 points.

In the subgroup of patients non-randomised to the VISIBLE I study who responded to treatment at week 14 and were included in the VISIBLE OLE study, an initial increase in quality of life was observed (an average change of 21.34 points between week 14 and week 62), while at week 110 of the follow-up period, the quality of life measured by the IBDQ questionnaire decreased by an average of 4.74 points.

Safety

Direct comparison of VED s.c. vs VED i.v. (VISIBLE I, GEMINI I)

In the VISIBLE I and GEMINI I studies, there were no deaths in either the VED or PLC group.

No significant differences were demonstrated between VED s.c. and VED i.v. in terms of the incidence of serious adverse events, overall adverse events (including treatment-related) and adverse events of special interest by system organ class (i.e. overall infections, nasopharyngitis, upper respiratory tract infections, sinusitis, urinary tract infections, malignancies and increased activity of ulcerative colitis).

Indirect comparison of VED s.c. vs PLC (VISIBLE I)

There were no statistically significant differences between VED s.c. and PLC in the incidence of: adverse events (65.1% vs 76.8%), treatment-related adverse events (26.4% vs 17.9%), serious adverse events (9.4% vs 10.7%), serious treatment-related adverse events (0.9% vs 0.0%).

Long-term safety analysis - VISIBLE OLE study

Overall, adverse events occurred in 61.1% of the patients, and 25.4% of them were related to VED s.c. treatment (the most common were: increased UC activity - 5%, injection site reaction - 3% and injection site erythema - 2.6%).

Serious adverse events were reported in 10.2% of the patients treated with VED s.c.

Additional safety information

According to the Summary of Product Characteristics for Entyvio, very common (≥1/10) adverse effects include nasopharyngitis, headache, joint pain.

Data from FDA 2020, ADRReports 2021 and WHO UMC 2021 databases and PRAC communications were considered as well.

Event categories reported in ADRReports or WHO UMC databases were identified as consistent with those presented in the analysis based on the included studies. Vedolizumab therapy is associated with general disorders and injection site conditions, gastrointestinal disorders, infections and parasitic infections, nervous system disorders as well as traumas, poisoning and complications after surgery.

Limitations

The main limitation of the reliability of the presented analysis is the lack of randomised trials directly comparing the assessed technology with the chosen comparator and the lack of observational studies on the use of VED s.c.

Proposed risk-sharing scheme [information protected as a trade secret]

[information protected as a trade secret]

Economic evaluation, including a cost-effectiveness estimation

Economic evaluation involves estimating and comparing the costs and health outcomes that may be associated with the administration of the new therapy to an individual patient instead of already reimbursed therapies.

The costs of therapy are estimated in Polish currency, and health outcomes are usually expressed in life-years gained (LYG) or quality-adjusted life years (QALY) as a result of the therapy.

By juxtaposing the values concerning the costs and outcomes of a new therapy and comparing them with the costs and outcomes of already reimbursed therapies, it is possible to answer the question whether the health outcome achieved in an individual patient due to a new therapy is associated with a higher cost compared to already reimbursed therapies.

The obtained results of the cost-effectiveness ratio are compared with the so-called cost-effectiveness threshold, i.e. a result that indicates that given the wealth of Poland (expressed in GDP), the maximum cost of the new therapy that is expected to produce a unit of health outcome (1 LYG or 1 QALY) compared to already available therapies should not exceed three times GDP per capita.

Currently, the cost-effectiveness threshold is PLN 166,758 / QALY (3 x PLN 55,586).

The cost-effectiveness ratio does not estimate or determine the value of life, but it only enables its assessment and on that basis, among other things, choosing the therapy related to potentially best outcome.

As part of the cost-effectiveness assessment, cost-minimisation analysis (CMA) was performed from the public payer perspective – the entity obliged to finance the interventions from public funds, i.e. the National Health Fund (NHF).

Entyvio administered subcutaneously (VED s.c.) was compared with Entyvio administered by intravenous infusion (VED i.v.) used in a dosing regimen according to the SmPC.

The following types of direct medical costs were included in the analysis:

- costs of doses of the compared interventions (VED s.c. vs VED i.v),
- costs of drug administration (intravenously and subcutaneously).

The results are presented in terms of patient population after the failure of treatment with TNF-alpha inhibitors and after the failure of standard treatment.

According to the basic analysis, the use of VED s.c. instead of VED i.v. in patients after the failure of (standard) anti-TNFα inhibitor therapy [information protected as a trade secret]

- VED vs standard treatment after the failure of standard therapy: [information protected as a trade secret]
- VED vs standard treatment after the failure of anti-TNFα inhibitor therapy: [information protected as a trade secret]

Limitations

The mentioned limitations of the analysis apply to the cost-utility analysis (CUA), which is an additional scenario. Cost-minimisation analysis (CMA) should be considered as the main analytical technique in the application.

Agency's own calculations

The Agency carried out its own calculations, taking into account alternative assumptions for the applicant's additional analysis, i.e. the CUA, which cause changes in the estimated ICUR values [information protected as a trade secret]

Indication whether the circumstances referred to in Art. 13 sec. 3 of the Act of 12 May 2011 on the reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices (Dz. U. /Journal of Laws/ of 2021, item 523 as amended) do arise;

If the applicant's clinical analysis does not include randomised clinical trials proving the superiority of the drug over health technologies already reimbursed, the official selling price of the drug must be calculated so that the cost of the drug to be reimbursed is not higher than the cost of the health technology with the most favourable cost–effectiveness ratio.

Due to the failure to present RCTs in the clinical analysis, the circumstances referred to in Article 13 of the Reimbursement Act do arise.

A calculation of the official selling price (OSP) based on the provisions of Art. 13 sec. 3 of the Reimbursement Act is given below.

The Entyvio official selling price at which the cost of its use is not higher than the cost of the comparator is: [information protected as a trade secret]

Assessment of the impact on the healthcare system, including the budget impact

Healthcare system impact assessment has two major parts.

First, the analysis of the impact on the payer's budget allows estimating the potential expenses associated with public reimbursement of the new therapy.

Estimates of expenses associated with the new therapy (the "tomorrow" scenario) are compared to how much is currently spent on treating a health problem (the "today" scenario). On this basis, it is possible to assess whether a new therapy will require more funds to treat that health problem or, rather, it will lead to savings in the payer's budget.

A budget impact assessment determines whether the payer has adequate funds to reimburse a

particular technology.

Healthcare system impact assessment in the second part answers the question of how the decision on the financing of a new therapy may influence the organisation of service provision (particularly in the context of adaptation to the requirements of the implementation of the new therapy) and the availability of other healthcare services.

The results of the applicant's budget impact analysis are presented over a two-year horizon. The analysis was carried out from the public payer (NHF) perspective and from the joint perspective (NHF and patient). The results of the analysis from both perspectives were similar.

The direct health costs – costs of drugs and their administration – were included.

The applicant has estimated the patient population that will use the proposed technology at: [information protected as a trade secret]

The results of the applicant's basic analysis indicate that the reimbursement of vedolizumab administered subcutaneously will entail: [information protected as a trade secret]

The results of the sensitivity analysis were consistent conclusions-wise with the results of the basic analysis.

Limitations

The main limitations of the budget impact analysis stem from the uncertainty of the population estimates, which are the input data for the analysis [information protected as a trade secret]

Agency's own calculations

No additional calculations were performed.

Comments on the proposed risk-sharing scheme

Vedolizumab administered subcutaneously is to be used in maintenance treatment so the proposed risk-sharing scheme conditions of a risk-sharing scheme for [information protected as a trade secret]

[information protected as a trade secret]

Comments on the drug programme

Patients with severe UC are qualified for the current drug programme. However, it should be emphasised that in the case of subpopulation of patients with insufficient response to standard treatment, an additional criterion of qualification is the Mayo scale score of >6 points, which indicates that patients with moderate to severe disease severity (as interpreted by the Mayo scale) may be qualified. For the remaining subpopulations, i.e. patients with intolerance or contraindications to standard therapy, the current drug programme does not refer to the Mayo scale.

The previous assessment of the drug programme for Entyvio (Report No. OT.4331.28.2020) revealed that changing the eligibility condition according to the Mayo score from >6 points to ≥6 points, analogous to the currently agreed drug programme, would make it possible to apply the vedolizumab treatment to all subpopulations with a moderate form of the disease (i.e. patients with insufficient response to standard treatment, intolerant to standard treatment and with contraindications to such treatment) - in the current assessment, this approach also appears to be reasonable.

Furthermore, it should be noted that the name of the proposed drug programme, i.e. "Treatment of ulcerative colitis (UC) (ICD-10 K51)", is not the same as the name of the current drug programme according to the current announcement of the Ministry of Health of 21 October 2021, i.e. "Treatment of patients with ulcerative colitis (UC) (ICD-10 K51)".

Discussion on the solutions proposed in the rationalisation analysis

The subject of the rationalisation analysis is the identification of a mechanism, the introduction of which will result in the release of public funds in an amount corresponding to at least the increase in costs resulting from a positive decision on the reimbursement of the health technology covered in this recommendation.

The rationalisation analysis is submitted if the budget impact analysis for the entity responsible for funding indicates an increase in reimbursement costs.

Not applicable.

Overview of recommendations issued in other countries in relation to the assessed technology

Ten clinical recommendations related to the indication named in the application were identified:

- Recommendations of the Working Group of the Polish National Consultant in Gastroenterology and the Polish Society of Gastroenterology - GRKK 2015.
- National Institute for Health and Care Excellence - NICE 2015/2019,
- American College of Gastroenterology - ACG 2019,
- British Society of Gastroenterology - BSG 2019,
- European Crohn's and Colitis Organisation - ECCO 2017/2018,
- French National Consensus Clinical Guideline - FNCCG 2016,
- Toronto Consensus - TC 2015,
- World Gastroenterology Organisation - WGO 2015.
- American Gastroenterological Association - AGA 2020,
- Deutsche Gesellschaft für Gastroenterologie, Verdauungs - und Stoffwechselkrankheiten - DGVS 2019.

In patients with a moderate to severe form of the disease for whom standard treatment has proved to be ineffective or inapplicable, the guidelines recommend TNF inhibitors and vedolizumab.

For patients in whom the TNF inhibitor therapy failed, it is recommended to switch to another inhibitor from this group or to use vedolizumab.

In addition to vedolizumab, the guidelines also indicate the possibility of using tofacitinib after both standard and TNF inhibitor treatment. For maintenance therapy, the most preferred option is to continue effective induction therapy.

Most guidelines do not specify the optimal duration of treatment with vedolizumab. According to the NICE 2015 guidelines for vedolizumab, treatment discontinuation may be considered in people with complete remission after 12 months of the therapy, with the possibility of resuming therapy with this drug after relapse.

The guidelines did not indicate the appropriate, recommended or preferred route of vedolizumab administration.

Reimbursement recommendations

The search for reimbursement recommendations found 4 documents issued in 2020 by HAS, SMC, CADTH and PBAC.

The recommendations were positive for the reimbursement of vedolizumab administered subcutaneously for the treatment of patients with moderate to severe ulcerative colitis. It was emphasised that Entyvio for subcutaneous administration does not provide clinical added value

compared to Entyvio for intravenous administration in the analysed indication (HAS) and that there is a clinical need for effective therapies for ulcerative colitis and the availability of a subcutaneous preparation will provide an additional maintenance therapy option (PBAC).

The conditional recommendation notes that reimbursement of the drug is justified, but under similar conditions as the reimbursement of the drug in intravenous form. Additionally, therapy with subcutaneous vedolizumab should only be initiated in patients who have achieved clinical response after induction therapy with vedolizumab (for intravenous administration at 300 mg) and the cost of the treatment plan with subcutaneous vedolizumab should not exceed the cost of the treatment plan with the cheapest biopharmaceutical currently reimbursed for the treatment of UC (CADTH). [information protected as a trade secret]

Legal basis for the recommendation

The recommendation was prepared based on the order of the Minister of Health of 13 October 2021 (ref. no.: PLR.4500.1688.2021.14.PTO) concerning the preparation of the President's recommendation on the assessment of Entyvio (vedolizumab) under the drug programme "Treatment of ulcerative colitis (UC) (ICD-10 K51)" pursuant to Art. 35 sec. 1 of the Act of 12 May 2011 on the reimbursement of drugs, foodstuffs intended for particular nutritional uses and medical devices (Dz. U. /Journal of Laws/ of 2021, item 523 as amended), having obtained Position of the Transparency Council No. 141/2021 of 20 December 2021 on the assessment of Entyvio (vedolizumab) under the drug programme "Treatment of ulcerative colitis (UC) (ICD-10 K51)"

References

1. Position of the Transparency Council No. 141/2021 of 20 December 2021 on the assessment of Entyvio (vedolizumab) under the drug programme "Treatment of ulcerative colitis (UC) (ICD-10 K51)"
2. Report No. OT.4231.50.2021 Application for the reimbursement of Entyvio (vedolizumab) in the indication: under the drug programme "Treatment of ulcerative colitis (UC) (ICD-10 K51)"