Recommendation No. 125/2021 of 17 November 2021 of the President of the Agency for Health Technology Assessment and Tariff System on the assessment of Taltz (ixekizumab) under the drug programme "Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)"

The President of the Agency recommends the reimbursement of Taltz (ixekizumab) solution for injection, 80 mg/ml, 2 injections 1 ml, GTIN code: 05909991282950 in the indication: under the B.82 drug programme "Treatment of patients with severe, active axial spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M 46.8)" in the existing limit group "1184.0, Ixekizumab" and dispensing it free of charge provided that:

- the costs of treatment with ixekizumab are reduced so that they do not exceed the costs of treatment with the cheapest TNF-alpha inhibitor reimbursed in the indicated drug programme,
- it is used in a patient population consistent with the registered indication, i.e. in axial spondyloarthropathy without radiographic changes characteristic of AS (nr-axSpA).

Grounds for the recommendation

Taking into account the position of the Transparency Council, available scientific evidence, clinical guidelines and reimbursement recommendations, the President of the Agency considers the reimbursement of Taltz (ixekizumab) justified under the above-mentioned conditions.

There are currently two TNF-alpha (iTNF) inhibitors available in the B.82 drug programme - etanercept (ETA) and certolizumab pegol (CER). Ixekizumab (IKS), as an interleukin-17 (iIL-17) inhibitor, would be an additional treatment option for patients eligible for the drug programme and the first option for patients with contraindications to, or after the failure of, currently reimbursed TNF-alpha inhibitors.

The results of the clinical analysis showed a higher efficacy of IKS versus placebo. At the same time, no advantage of IKS over TNF-alpha inhibitors reimbursed in the drug programme – ETA and CER – has been demonstrated. Because of the absence of confirmed additional health outcomes, the cost of IKS therapy should not exceed the cost of treatment with the cheapest technology currently used in the drug programme.

It should be taken into account that no data were found on the efficacy of the proposed technology in the population of patients with peripheral SpA. Thus, no scientific evidence has so far been presented to justify the funding of IKS for the treatment of peripheral spondyloarthropathy.

According to the applicant's estimates, the use of IKS is [information protected as a trade secret] compared to ETA and [information protected as a trade secret] compared to CER. The maximum net sales price at which the cost of using IKS is not higher than the cost of using ETA within a time horizon of 1.5 years is [information protected as a trade secret] – it is [information protected as a trade secret] than the proposed net sales price [information protected as a trade secret].

According to the results of the applicant's budget impact analysis, the reimbursement of Taltz (ixekizumab) will be associated with [information protected as a trade secret]. The expenditure of the NHF, when the RSS is considered, will be: [information protected as a trade secret].

Clinical recommendations include the use of IKS in patients with axSpA after iTNF failure or intolerance, in patients with contraindications to iTNF, and as an alternative to iTNF. The reimbursement recommendations highlight that Taltz does not provide additional clinical value compared to iTNF in the assessed indication.

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:

- Taltz (ixekizumab) solution for injection, 80 mg/ml, 2, 1 ml injectors, GTIN code: 05909991282950; proposed net sales price [information protected as a trade secret]

under the B.82 drug programme "Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M 46.8)".

Proposed payment and dispensing category: patient payment level – free of charge, in the above-indicated drug programme, in the existing limit group 1184.0, Ixekizumab. The applicant has submitted a proposal for a risk-sharing scheme.

Health problem

Inflammatory spondyloarthropathies (SpAs) are a group of diseases in which there is an inflammation of the joints of the spine and paravertebral tissues, peripheral joints, tendon attachments and inflammatory changes in many other systems and organs. The cause of SpA is not known. It has two forms: *axial spondyloarthropathy* (axSpA), in which spinal symptoms predominate, and *peripheral spondyloarthropathy* (pSpA) manifested mainly by arthritis (usually asymmetrical) of the lower limbs, sacroiliac joints as well as tendon and finger inflammation.

Non-radiographic axSpA affects approximately from 0.1-0.5% to even more than 1% of the population. In the SpA patient population, the proportion of patients meeting the ASAS classification criteria for pSpA was approximately 25%.

Disease burden and its impact on quality of life in both radiographic and non-radiographic forms is not significantly different.

Alternative health technology

Treatment of SpA is currently funded in Poland under the B.82 drug programme "Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)", which includes etanercept (axial form) and certolizumab pegol (axial and peripheral form; in patients with peripheral arthritis, it can be combined with methotrexate or sulfasalazine).

In the indication in question, the applicant identified etanercept (ETA) and certolizumab pegol (CER) used in the B.82 drug programme as alternative technologies to ixekizumab (IKS). Etanercept and certolizumab pegol are currently used and reimbursed in the assessed indication and will potentially be replaced by IKS, thus the choice of comparators was reasonable.

In the population with the failure of treatment with TNF-a inhibitors in the B.82 drug programme, the

applicant indicated best supportive care (BSC) as a comparator, which is defined as "mainly the use of NSAIDs, corticosteroids or typical disease-modifying drugs". Given the lack of reimbursable active treatments and the use of the indicated drugs in treatment stages prior to inclusion in the B.82 drug programme, it should be considered that this treatment would correspond to a lack of treatment.

Description of the proposed intervention

Ixekizumab (IKS) is a monoclonal antibody belonging to immunoglobulin G (IgG4) subclass 4 that binds to interleukin 17A (IL-17A). Elevated IL-17A levels play a role in the pathogenesis of axial spondyloarthropathy (axSpA).

According to the Summary of Product Characteristics (SmPC), Taltz is indicated mainly for the treatment of adult patients with active axSpA without radiographic changes and with objective signs of inflammation, as evidenced by elevated C-reactive protein (CRP) or magnetic resonance imaging (MRI) findings, who have had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs).

According to the SmPC for Taltz, the indication registered for IKS includes non-radiographic axSpA (nr-axSpA). At the same time, the proposed indication concerns both the axial and peripheral forms of the disease, so it is broader than the registered indication.

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

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.

The aim of the applicant's clinical analysis was to evaluate the efficacy and safety of IKS used in patients with SpA without radiographic changes characteristic of AS compared with reimbursable optional technologies.

The applicant did not find studies that directly compare IKS with comparators – ETA or CER – in systematic literature research. The results of the COAST-X randomised clinical trial (RCT) comparing the use of IKS versus PLC in a patient population with nr-axSpA are presented. BSC was used in both arms. A blinded phase lasted 16 weeks, after which drugs other than biopharmaceuticals were adjusted and patients had the option to move into an open phase. The endpoints assessed included the occurrence of ASAS40 response and the change compared to the initial value of ASDAS-CRP, BASDAI, BASFI, CRP (mg/L), SPARCC on MRI of the sacroiliac joints. Quality of life was assessed using the SF-36 PCS questionnaire. The safety profile was also assessed. The overall risk of bias in the Jadad scale was graded as low.

According to Deodhar 2020, the ASAS40 (Assessment of SpondyloArthritis international Society-40) dichotomous endpoint is defined as an improvement of at least 40% and an absolute improvement from *baseline* of 2 or more units (in the range of 0-10) in at least three of the four domains (assessment of overall disease activity by patient, spinal pain, physical functioning and spinal inflammation) with no deterioration in any of the other domains. The occurrence of the endpoint in a patient can be interpreted as an improvement in their health status. ASAS40 is a surrogate endpoint.

The analysis also presented [information protected as a trade secret]

The applicant's analysis states that no observational studies were found from which it would be possible to assess the effectiveness and safety of the intervention versus the comparators.

Efficacy

No studies directly comparing IKS vs ETA or IKS vs CER were found.

Direct comparison of IKS vs PLC - RCT COAST-X (Deodhar 2020, Walsh 2020)

The results are presented for the IKS Q4W arm (n = 96), in which IKS was administered at 80 mg *s.c.* every 4 weeks, compared to the PLC arm (n = 105). The follow-up period is 16 weeks – the blinded phase of the study.

For the ASAS40 endpoint, the response in the IKS Q4W arm occurred in 35% of patients (34/96) and in the PLC arm in 19% of patients (20/105). The odds ratio was OR 2.36 (95%CI: 1.23; 4.51; p = 0.0094). In contrast, ASDAS <2.1 ("low disease activity") occurred in 28% of patients (26/96) in the IKS Q4W arm and in 12% of patients (13/105) in the PLC arm. The odds ratio was OR 2.73 (95%CI: 1.30; 5.76; p = 0.0080).

Walsh 2020 presents the results of a quality-of-life assessment using the EQ-5D-5L questionnaire. During the 16th week of the follow-up period, the difference from the initial values expressed in terms of the least squares mean (LSM) in the IKS Q4W arm 0.19, and in the PLC arm 0.11. The applicant reports that the mean difference was MD = 0.08 and it is a statistically significant result (p = 0.011).

[information protected as a trade secret]

[information protected as a trade secret]

Safety

Direct comparison of IKS vs PLC – RCT COAST-X

In the COAST-X study, during the 52nd week of the follow-up period, no deaths were reported in the IKS treatment group.

In the IKS Q4W arm, for a follow-up period of 52 weeks, adverse events (AEs) occurring during treatment were observed in 65.6% of the patients (63/96). Serious AEs arising during treatment and AEs leading to treatment discontinuation were observed in 1 and 1 patient, respectively. Infections were observed in 39.6% of patients (38/96) – these were the most common AEs.

[information protected as a trade secret]

Additional efficacy and safety analysis

Assessment of effectiveness

The applicant has not identified effectiveness data.

Information based on SmPC

According to the SmPC for Taltz (last updated: 27 August 2021), the most commonly reported adverse reactions to IKS were injection site reactions (15.5%) and upper respiratory tract infections (16.4%) (most commonly rhinosinusitis). In addition, common (occurring ≥1/100 to <1/10) adverse reactions after IKS were: fungal infection, herpes simplex virus infection (mucocutaneous); mouth

and throat pain; nausea.

Information based on safety communications on the websites of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (URPL), the European Medicines Agency (EMA) and the Food and Drug Administration (FDA)

No safety communications regarding IKS were found on the URPL, EMA and FDA websites.

Limitations

The main limitation of the applicant's clinical analysis, which significantly affects the conclusion, is the lack of results from randomised clinical trials directly comparing the efficacy and safety of IKS versus ETA or CER in the population covered by the application.

In the COAST-X study, the initial dosage of IKS was inconsistent with the registered one. The results of the study indicate that patients with IKS Q4W who initially received 160 mg compared to the ones with 80 mg had lower ASAS40 response rates during both analysed follow-up periods (33% vs 38% and 29% vs 32%, respectively). Thus, the average efficacy for IKS Q4W reported in the aforementioned study may not correspond to that obtained for the registered dosage, which is consistent with the assessed drug programme.

[information protected as a trade secret]

Furthermore, no clinical studies were found on the use of the proposed technology in the population of patients with peripheral spondyloarthropathy.

Other limitations are presented in the Agency Verification Analysis.

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.

Juxtaposing the values concerning the costs and outcomes of a new therapy and comparing them to the costs and outcomes of already reimbursed therapies allows answering the question of whether the health outcome achieved in an individual patient owing to a new therapy is associated with a higher cost in comparison with 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 (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 the use of this assessment to choose the therapy associated with the potential best use of the currently available resources.

The cost-effectiveness of ixekizumab (IKS) therapy for the treatment of spondyloarthropathy in Poland within the B.82 drug programme "Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)" was assessed using *cost-minimisation analysis* (CMA).

The analysis was carried out from the public payer perspective (NHF) and the joint perspective (NHF and patient). The results of the analyses from the joint perspective are the same as the results from the NHF perspective, so the decision against citing them was made.

The CMA was conducted based on data on the comparison of efficacy and safety of IKS versus CER and versus ETA taken from [information protected as a trade secret]. The analysis was performed for a time horizon of 1.5 years, indicating that after 6 months. the costs of the compared therapies stabilise. The cycle length adopted in the model is 3 months and coincides with the treatment monitoring period. The following were considered to be the costs differentiating the assessed health technologies: drug costs, administration costs.

According to the applicant's estimates, the use of IKS instead of ETA is [information protected as a trade secret]. On the other hand, the use of IKS instead of CER is [information protected as a trade secret].

In the absence of randomised clinical trials proving the superiority of the proposed health technology over the currently reimbursed comparator, the circumstances referred to in Art. 13 sec. 3 of the Reimbursement Act do arise. The value of the official selling price of Taltz at which the cost of its use is not higher than the cost of using the technology so far reimbursed in the indication analysed with the most favourable cost-effectiveness ratio, i.e. ETA, is [information protected as a trade secret]. The maximum net sales price is [information protected as a trade secret] than the proposed net sales price.

The sensitivity analysis tested the impact of alternative parameter values and scenarios on the CMA results. The biggest impact on incremental costs associated with replacing CER and ETA with IKS was the inclusion of the assumptions regarding: [information protected as a trade secret]. None of the parameters tested led to changing the conclusions.

Limitations

Key limitations of the applicant's analysis:

- The applicant's economic analysis did not present results for one part of the proposed population, i.e. patients with peripheral SpA who meet other provisions of the assessed drug programme.
- The applicant's clinical analysis did not present studies directly comparing the studied intervention with the selected active comparators (CER, ETA), so there is considerable uncertainty regarding the applicant's choice of CMA analytical technique, the primary objective of which is to demonstrate equivalent efficacy and safety of the technology relative to the comparators. [information protected as a trade secret]
- To compare IKS vs BSC, cost-utility analysis (CUA) was carried out; however, due to the lack of scientific evidence for IKS in the population of patients with intolerance or ineffectiveness of previous treatment with TNF-alpha inhibitors who meet other provisions of the assessed drug programme, the presented CUA was found unjustified.

Other limitations are presented in the Agency Verification Analysis.

Agency's own calculations

In the basic analysis, the applicant assumed prices for ETA only on the basis of one month – December 2020, and for CER only on the basis of information from tenders.

Taking into account the latest data received from the National Health Fund for 2021, the use of IKS [information protected as a trade secret] is [information protected as a trade secret] compared to ETA and [information protected as a trade secret] compared to CER.

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) 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.

The clinical analysis does not include randomised clinical trials proving the superiority of the technology covered in this recommendation over the comparators so, in the Agency's opinion, the circumstances referred to in Art. 13 of the Reimbursement Act do arise.

The official selling price (OSP) of Taltz at which the cost of its use is not higher than the cost of using

the technology already reimbursed in the indication analysed with the most favourable cost-effectiveness ratio (ETA was used in the applicant's analysis) 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 the expenses associated with the new therapy (the "tomorrow" scenario) are compared to how much is currently spent on treating the health problem (the "today" scenario). On this basis, it is possible to assess whether a new therapy will require more resources allocated to the treatment of the given health problem or whether it will result in savings in the payer's budget.

A budget impact assessment determines whether a payer has adequate resources to reimburse a particular technology.

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

Budget impact analysis (BIA) was performed to estimate the public payer's expenditure in the event of a positive decision on the public funding of ixekizumab (IKS) under the B.82 drug programme "Treatment of patients with severe active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)".

The analysis was performed from the public payer perspective (NHF) and from the joint perspective (NHF and patient), and the results of both analyses are the same. A two-year time horizon was adopted.

Two scenarios were compared: the existing and the new one. The existing scenario depicted the current situation in which the proposed technology is not publicly funded in the proposed indication, while patients in the B.82 programme receive certolizumab pegol (CER) or etanercept (ETA). The new scenario assumes a situation where Taltz (IKS) is reimbursed in the proposed indication, within the existing limit group and will partially take over CER and ETA shares.

The number of patients who will use the applied technology in the new scenario was estimated based on the average annual increase in the number of patients treated in the B.82 drug programme on [information protected as a trade secret] the first year and [information protected as a trade secret] the second year.

According to the results of the basic analysis, the reimbursement of Taltz (ixekizumab) will be related to [information protected as a trade secret].

In the applicant's analysis, it was assumed that the proposed technology would only take up the share of active therapies reimbursed under the B.82 drug programme. However, patients with contraindications to TNF-alpha inhibitors and patients after failure or intolerance of treatment with TNF-alpha inhibitor(s) who were not included in the B.82 programme were omitted.

The applicant has estimated the number of patients to be [information protected as a trade secret]

As part of the BIA, the applicant carried out the analysis of extreme scenarios and alternative

scenarios of the parameter values. The results showed that the inclusion of [information protected as a trade secret] had the highest impact.

Limitations

The main limitations of the analysis relate to the assumptions involved in estimating the size of the target population. The applicant based its estimates on the average annual increase in the number of patients treated in the B.82 drug programme, calculated on the basis of data from the National Health Fund Reports for 2017-2020. The estimates do not take into account patients currently treated under this programme, while, according to the proposed drug programme, it is possible to switch from one therapy to another within this programme.

Other limitations are presented in the Agency Verification Analysis.

Agency's own calculations

In the Agency Verification Analysis of the applicant, similarly to the assumptions of the economic analysis, CER and ETA costs were estimated based on the Department of Drug Administration communication covering the period from January 2018 to December 2020 (ETA) and public tenders (CER). Based on the information that the Agency received directly from the NHF, in 2021, the average cost per 1 mg was: ETA [information protected as a trade secret] and CER [information protected as a trade secret].

Based on the applicant's electronic model, calculations were made by changing the cost of 1 mg of CER and ETA with other parameters unchanged. Estimates indicate that incremental costs [information protected as a trade secret] than in the basic analysis of the applicant and will amount to [information protected as a trade secret] in the first year and [information protected as a trade secret] in the second year of reimbursement.

Comments on the proposed risk-sharing scheme [information protected as a trade secret]

Comments on the drug programme

The main aim of therapy in patients with SpA is to improve their quality of life. It is proposed to add the assessment of patients' quality of life during the eligibility process and during treatment monitoring in the programme to obtain real data from Polish clinical practice.

In the evaluated drug programme, the section on dosing indicated: "In patients with peripheral arthritis, the combined use of certolizumab pegol and ixekizumab with methotrexate or sulfasalazine at clinically effective and well-tolerated doses should be considered". It is suggested to clarify this provision in line with current therapeutic management in this patient group: "In patients with peripheral arthritis, certolizumab pegol or ixekizumab should be considered to be used together with methotrexate or sulfasalazine at clinically effective and well-tolerated doses".

The IKS dosage refers to the SmPC of Taltz, which describes dosage for part of the proposed indication (i.e. nr-axSpA). Therefore, no dosage is indicated for the peripheral form of the disease, which should also be added.

Clinical experts point out the following: shortening the duration of NSAID intake
in the eligibility criteria, adjusting the dose of sulphasalazine from 2 g to 2-4 g/day, the criteria of receiving adequate response to treatment and determining the order in which drugs are to be administered. For the full text of clinical experts' comments, see the Agency Verification Analysis.

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 shall be submitted if the budget impact analysis for the entity obliged to finance benefits from public funds shows an increase in reimbursement costs. [information protected as a trade secret]

Overview of recommendations in relation to the assessed technology

Clinical recommendations

According to the latest guidelines, IKS is recommended for use in patients with axSpA after iTNF failure or intolerance or in patients with contraindications to iTNF (UpToDate 2021, ACR/SAA/SRTN 2019). One guideline recommends IKS in patients with pSpA resistant to sDMARDs as an alternative to iTNF (with peripheral arthritis) or after failure of NSAID and GCS treatment on par with iTNF (with tendonitis) (UpToDate 2021).

Other guidelines indicate the possibility of using iTNF or iIL-17 (no substance indicated) in patients with axSpA after unsuccessful treatment with NSAIDs or first-line biological therapy, most commonly iTNF (SER 2018, SFR 2018, EULAR 2016). In addition, one guideline indicated that biopharmaceuticals, including IL-17 inhibitor (no substance was named), can also be used in patients with pSpA after failure of conventional treatment (SFR 2018).

Reimbursement recommendations

Three reimbursement recommendations related to the assessed technology were identified – two positive (HAS 2020, G-BA 2021) and one conditionally positive (NICE 2021). The recommendations highlighted that Taltz does not provide additional clinical value compared to TNF inhibitors in the treatment of the indications considered. Ixekizumab was indicated to be effective compared to the placebo.

According to the information provided by the applicant, Taltz is financed in [information protected as a trade secret]. In all countries, the reimbursement is [information protected as a trade secret]

Legal basis for the recommendation

The recommendation was prepared on the basis of the Order of the Minister of Health of 27 August 2021 (ref. no.: PLR.4500.705.2021.15.RBO) regarding the preparation of the President's recommendation on the assessment of the drug: Taltz (ixekizumab) solution for injection, 80 mg/ml, 2 injections 1 ml, GTIN code: 05909991282950, in the indication: within the framework of the B.82 drug programme "Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)" 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), having received Position of the Transparency Council No. 125/2021 of 15 November 2021 on the assessment of Taltz (ixekizumab) under the drug programme "Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)".

References

1. Position of the Transparency Council No. 125/2021 of 15 November 2021 on the assessment of Taltz (ixekizumab) under the drug programme "Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)".
2. Report No. OT.4231.38.2021 "Application for the reimbursement of Taltz (ixekizumab) within the framework of the drug programme »Treatment of patients with active spondyloarthropathy (SpA) without radiographic changes characteristic of AS (ICD-10 M46.8)« Verification analysis" Completion date: 4 November 2021.