Recommendation No. 19/2021

of 17 February 2021

of the President of the Agency for Health Technology Assessment and Tariff System

on the reimbursement of the Farxiga drug (dapagliflozin) in the following indication: chronic heart failure in adult patients with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists

The President of the Agency for Health Technology Assessment and Tariff System does not recommend that the Farxiga drug (dapagliflozin) be reimbursed in the following indication: chronic heart failure in adult patients with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists under the current conditions.

Explanation for recommendation

The President of the Agency, taking into account the position of the Transparency Council, available scientific evidence, clinical guidelines considers the public financing of the technology named in the application to be unjustified under the current conditions.

The results of a clinical analysis based on one randomised trial (DAPA-HF) conducted in a population of patients with diagnosed, documented, and symptomatic (NYHA II-IV) heart failure with reduced ejection fraction for at least 2 months, and treated with medications and/or with the use of an assist device, if indicated.

It was considered that the effect of dapagliflozin on the primary endpoint was generally consistent across pre-specified subgroups, including in patients without diabetes at the start of the trial, but it seems that the effect on the population of patients belonging to NYHA class III or IV was less favourable (the result was not statistically significant) compared to the population of patients belonging to NYHA class II. The identified discrepancies in the consistency of the results are also related to the geographical region. The analyses show that the benefit of using dapagliflozin in the European region is the lowest, with the result not

being statistically significant, whereas for the South America and Asia regions, the benefit is statistically significant and the effect is higher. In addition, the following characteristics appear to be of importance as well: sex, ejection fraction, history of hospitalisation for heart failure, and presence of atrial fibrillation or flutter in the ECG.

When interpreting the results, it should also be taken into account that the population in question is composed of patients belonging to the NYHA heart failure classes of II to IV; however, in line with the trial characteristics and information provided in the current SmPC, information on patients suffering from class IV heart failure is limited, and 0.8% of patients suffering from class IV heart failure were included in the intervention group of the trial.

It should also be considered that the budget impact analysis points to a considerable burden on the payer's budget and does not include solutions to prevent undue risk. Also, some of the parameters used by the applicant to estimate the target population may raise doubts. The percentage of patients willing to pay extra for Forxiga was adopted based on a price elasticity survey carried out on a group of diabetes specialists and patients suffering from diabetes, which is a limitation in itself and involves estimation uncertainty. The parameter was not tested under sensitivity analysis either.

In view of the position of the Transparency Council and due to the importance of the health problem and possible benefits to be derived from a lower risk of hospitalisation and death from cardiovascular health problems, the President of the Agency finds it justified to enable the public financing of dapagliflozin in the indication applied for provided that a risk sharing agreement specifying a lower unit cost of therapy and introducing maximum expenses incurred by the public payer is suggested.

Subject of the application

The order of the Minister of Health concerns the assessment of the appropriateness of public financing of a medicinal product:

- Forxiga (dapagliflozin), coated tablets, 10 mg, 30 tablets (30 x 1), EAN code: 05909990975884 – for which the proposed net selling price is (trade secret);
- Forxiga (dapagliflozin), coated tablets, 10 mg, 14 tablets (14 x 1), EAN code: 05909990975853 – for which the proposed net selling price is (trade secret);

Proposed payment and dispensing category: (trade secret), prescription drug in the indication defined by a clinical condition, under (trade secret)

Health problem

Heart failure (HF) is a condition, in which cardiac dysfunction leads to reduced cardiac output compared to the metabolic demand of body's tissues or in which the proper cardiac output is maintained by increasing filling pressure, which causes clinical symptoms, including, in particular, reduced exercise tolerance and excessive sodium and water retention.

50% of patients belonging to New York Heart Association (NYHA) class IV dies within a year. Mortality in the general population of patients with chronic heart failure (regardless of aetiology) is approx. 10% per year. The ESC-HF pilot study demonstrated that 12-month all-cause mortality rates for hospitalised and ambulatory HF patients were 17% and 7% respectively. Approx. 60% of men and approx. 40% of women die within 5 years. Median survival from onset of clinical symptoms is 6 years.

In patients with heart failure with reduced ejection fraction (HFrEF), the mortality rate per year is estimated at 10-15%.

Alternative health technology

In connection with the indication in question, dapagliflozin will not replace angiotensin-converting-enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), beta blockers, or mineralocorticoid receptor antagonists (MRAs), in clinical practice, so these drugs cannot be used as a comparator for the evaluated intervention. If dapagliflozin is added to ACEIs (or ARBs) or beta blockers, the population in question includes patients with contraindications to MRAs, meaning that MRAs cannot be used as a comparator for dapagliflozin.

Given the absence of a reimbursable health technology to treat adults with chronic heart failure with left ventricular ejection fraction (LVEF)below 40% and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on – ACEIs (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists, it was concluded that the right comparator for dapagliflozin in the analysed indication is to continue the current standard therapy, including the use of CEIs (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists (placebo). Dapagliflozin therapy with be added to the existing treatment scheme.

Description of the benefit named in the application

Dapagliflozin is a selective and reversible sodium-glucose co-transporter-2 (SGLT-2) inhibitor. SGLT2 is selectively expressed in kidneys, with no such expression being present in over 70 other types of tissues (mainly in the liver, muscle tissue, fat tissue, breast, bladder, or brain). SGLT2 is the main transporter responsible for the reabsorption of glucose from glomerular filtration into the blood.

According to the Summary of Product Characteristics (SmPC), Forxiga is indicated in adults:

- for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:
    - as monotherapy when metformin is considered inappropriate due to intolerance;
    - in addition to other medicinal products for the treatment of type 2 diabetes;
- for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥ 27 kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy; and
- for the treatment of heart failure with reduced ejection fraction.

The indication in question is the narrowing of the last indication for patients with chronic heart failure with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists.

Evaluation of efficacy (clinical and practical) and safety

This evaluation consists of collecting data on the health consequences (efficacy and safety) of a new therapy for a given health problem and other therapies that are currently publicly funded and represent alternative treatments available for the particular health problem. Subsequently, this evaluation involves determining the reliability of the collected data and comparing the efficacy and safety results of the new therapy against therapies that are already available for the treatment of the health problem in question.

Based on the above, the assessment of efficacy and safety provides an answer to the question of the measure of health outcome (in terms of both efficacy and safety) to be expected for the new therapy compared to other therapeutic options considered.

The applicant's analysis included two secondary studies (Aimo 2020 and Zheng 2020), described in two publications, whose main objective was to evaluate the efficacy of sacubitril/valsartan, vericiguat, and SGLT-2 inhibitors in the population of patients with heart failure with reduced ejection fraction and to perform a comprehensive assessment of the action of dapagliflozin in HF patients with or without type 2 diabetes. These secondary studies were of low quality according to the AMSTRA 2 tool as a result of, in particular, failure to provide a list of studies excluded from the review and deficiencies in other domains such as failure to provide the criteria for study selection.

The core of the clinical analysis is one RCT DAPA-HF trial carried out in patients with diagnosed, documented, and symptomatic (NYHA II-IV) heart failure with reduced ejection fraction (HFrEF) for at least 2 months, and treated with medications and/or with the use of an assist device, if indicated. Median follow-up was 18.2 months (0 - 27.8 months). The trial included 4,744 patients. The risk of bias was evaluated to be low for most domains except for "risk of bias in selection of the reported result", where the risk was assessed to be unknown due to the fact that results were described for all endpoints given in the publication but not assumed in the study – there were additional endpoints in the study according to the protocol.

The following parameters were used to evaluate efficacy:

- HR – *Hazard ratio*;
- OR – *Odds ratio*.

The quality of life assessment was performed for a group of 4,443 patients (93.7% of the total population) based on the Kansas City Cardiomyopathy Questionnaire (KCCQ).

Clinical efficacy

Primary studies

According to the DAPA-HF results, the use of dapagliflozin compared with placebo was statistically significantly associated with:

- a 26% lower risk of worsening heart failure (hospitalisation or urgent visit with the introduction of intravenous heart failure treatment) or death from cardiovascular causes - HR=0.74 (95% CI: 0.65; 0.85);
- a 30% lower risk of hospitalisation for heart failure - HR=0.70 (95% CI: 0.59; 0.83);
- an 18% lower risk of death from cardiovascular causes - HR=0.82 (95% CI: 0.69; 0.98);
- a 17% lower risk of all-cause mortality - HR=0.83 (95% CI: 0.71; 0.97);
- a 25% lower risk of hospitalisation for heart failure or death from cardiovascular causes - HR 0.75 (95% CI 0.65; 0.85).

The trial analysed the effect of dapagliflozin on the primary endpoint broken down by predefined subgroups. The results showed that the effect of the therapy was similar to the general population for most subgroups, including in patients without diabetes at the start of the trial, but it seems that the patients belonging to NYHA class III or IV benefited to a lesser extent than those belonging to class II. Large discrepancies in the consistency of the results are also related to the geographical region. The analyses show that the dapagliflozin benefit in the European region is the lowest, with the result not being statistically significant, whereas for the South America and Asia regions, the benefit is statistically significant and the effect is higher. In addition, the following characteristics appear to be of importance as well: sex, ejection fraction, history of hospitalisation for heart failure, and presence of atrial fibrillation or flutter in the ECG.

In line with the quality of life assessement, the patients treated with dapagliflozin saw a statistically significant improvement in mean KCCQ-TSS, CSS, OSS values after 4 months (these values were 1.9,

1.8, and 1.7 points higher than placebo respectively). The differences between dapagliflozin and placebo increased over time, with the mean differences after 8 months being 2.8, 2.5, and 2.3 points higher for dapagliflozin compared to placebo respectively.

Secondary studies

Aimo 2020

According to the results of meta-analysis, all available therapies brought a survival benefit for HFrEF patients. SGLT2is were characterised by the largest relative reduction in the incidence of the primary composite endpoint (death from cardiovascular (CV) causes or first HF hospitalisation) compared to the standard therapy (HR 0.74, 95% CI 0.67; 0.81; interpretation: the use of SGLT2 inhibitors was associated with a statistically significant reduction (approx. 26%) in the risk of death or hospitalisation compared to the standard therapy). The analysis of individual endpoints also demonstrated superiority in terms of the reduction in the risk of death HR 0.84 [0.74; 0.95] and hospitalisation for heart failure HR 0.69 [0.62; 0.77], with the interpretation being consistent with the results for the composite endpoint.

The indirect comparison reveals that dapagliflozin is not associated with a statistically significantly lower risk of death from cardiovascular causes or HF hospitalisation or death from cardiovascular causes alone compared to sacubitril/valsartan or vericiguat. The risk of hospitalisation for HF does not significantly differ between the patients treated with dapagliflozin or sacubitril/valsartan, whereas dapagliflozin was superior to vericiguat.

A general advantage over the standard therapy was demonstrated. For dapagliflozin, the determined probability of being the best among the therapies evaluated, expressed as the SUCRA score, was:

- 96% – in terms of the composite endpoint;
- 100% – in terms of absolute risk reduction;
- 84% – in terms of death from cardiovascular causes;
- 97% – in terms of hospitalisation for heart failure.

Zheng 2020

The results of the meta-analysis demonstrated that compared to placebo, the use of dapagliflozin is associated with a statistically significant reduction (28%) in the risk of hospitalisation for heart failure (RR=0.72 [95%CI: 0.63; 0.82]) and a statistically significant reduction (17%) in the risk of all-cause mortality (RR=0.83 [94%CI: 0.74; 0.94]).

In addition, there was a statistically significant reduction (14%) in the risk of cardiovascular death (RR=0.86 [95%CI: 0.74; 0.99]) and a 12% reduction in the risk of major adverse cardiovascular events (MACE) (RR=0.88 [95%CI: 0.78; 0.99]) in the group of patients using dapagliflozin compared to placebo.

Safety

In line with the DAPA-HF results, the use of dapagliflozin was associated with a statistically significant lower incidence of:

- major renal adverse events – 1.6% vs 2.7%;
- heart failure – the odds of the event were 29% lower, OR=0.71 (95% CI: 0.60; 0.85);
- ventricular tachycardia – the odds of the event were 38% lower, OR=0.62 (95% CI: 0.40; 0.96);
- acute kidney injury – the odds of the event were 50% lower, OR=0.71 (95% CI: 0.30; 0.96).

There were no statistically significant differences in terms of, for example, adverse events leading to the discontinuation of treatment, death, major adverse events, or treatment-related adverse events.

Zheng 2020

In terms of safety, the meta-analysis of three trials (including DAPA-HF and DEFINE-HF trials) pointed to no statistically significant difference between the analysed groups in terms of the incidence of hypoglycaemia, fluid volume reduction, and renal diseases.

Additional efficacy and safety information

The message issued by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products points to the risk of Fournier gangrene if SGLT-2 inhibitor drugs are used. Patients who use the aforementioned inhibitors must be made aware that they have to see the doctor if they experience severe pain, tenderness, erythema, or swelling in the genital or perineal area combined with fever or malaise. If Fournier gangrene is suspected, the use of the SGLT-2 inhibitor must be discontinued and treatment must start immediately.

Limitations

The uncertainty of the presented results is affected by the following aspects:

- for effectiveness analysis, no studies meeting the review inclusion criteria were found, i.e. studies that evaluate the use of dapagliflozin in patients with chronic heart failure in the analysed population of patients in real-world clinical practice. The lack of independent observational studies at this stage is a natural consequence of waiting for the therapy to become widespread after the drug has been registered for a particular indication.
- in line with the methodology of the clinical trial included in the analysis, the efficacy of dapagliflozin was evaluated as an add-on therapy, i.e. it was added to the standard therapy used by the patients; the patients differed in the components of heart failure therapy; according to clinical practice guidelines, these differences may exist; however, submitting an application based on aggregate results may be a limitation in this case; in the analytical materials of the trial, no subgroup analyses were presented due to the standard therapies used;
- the population included in the trialmay correspond to the population in question in the partial scope of indication given that the application concerns patients with persistent heart failure symptoms despite the use of the therapy based on angiotensin-converting-enzyme inhibitors or, in the case of intolerance/counterindications, the therapy based on angiotensin receptor blocker and beta blockers and, if indicated, mineralocorticoid receptor antagonists. When analysing baseline population characteristics, none of the available materials included information on the percentage of multicomponent therapies used by the patients included in the trial. The most common drugs included beta blockers, which is consistent with practice. In the trial, the included patients also used glycosides originating from digitalis (pharmaco-therapeutic group whose use is not consistent with the application). Furthermore, a considerable group of patients were diagnosed with diabetes both before the trial and during the qualification phase, which was associated with the use of treatment targeted at lowering blood glucose levels (biguanides, sulphonylurea derivatives, DPP-4 inhibitors, gliptins, insulins).
- the cut-off point included in the application and concerning the qualification of patients based on the reduction in left ventricular ejection fraction is 40%, meanwhile ejection fraction for the patients included in the trial was lower by 10 percentage points on average. This limitation was not included in the SmPC. A reference in the clinical practice guidelines pointing to such percentage is also nowhere to be found, which means that such information is questionable, and so is the extrapolation of the results of the trial, which, in fact, was conducted on a population with essentially different characteristics;

- another point of the indication is the determination of NYHA heart failure class, which is to include patients belonging to class II to IV; however, in line with trial characteristics and information included in the current SmPC, information on patients suffering from class IV heart failure are limited, with 0.8% of such patients being included in the intervention group of the trial.

Proposed risk-sharing instruments

(trade secret)

Economic evaluation, including estimates of cost to health outcomes achieved

Economic evaluation involves estimating and comparing the costs and health outcomes that may be associated with using the new therapy for an individual patient in place of already reimbursed therapies.

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

By comparing the cost and outcome values of the new therapy to the costs and outcomes of already reimbursed therapies, one can answer the question of whether the health outcome achieved for an individual patient with the new therapy is associated with a higher cost compared to already reimbursed therapies.

The obtained results of the cost to health outcome ratio are compared with the use of the so-called break-even point, i.e. a result that indicates that given the wealth of our country (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 the GDP per capita.

Currently, the break-even point is PLN 155,514 (3 x PLN 51,838).

The cost to health outcome ratio does not estimate or determine the value of life, it only enables its assessment and, among others, its use to choose the therapy associated with the potential best use of the currently available resources.

The objective of economic analysis was to investigate the cost-effectiveness of the public financing of the dapagliflozin (Forxiga) therapy in Poland compared to the standard therapy given to adults suffering from chronic heart failure with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists (MRAs). To do so, lifetime cost–utility analysis was performed from both the public payer's perspective and a joint perspective (NFZ and patient).

The following cost categories were included in the analysis:

- dapagliflozin costs;
- standard treatment costs;
- diabetes comorbidity costs;
- costs of cardiovascular events and treatment of adverse events.

Standard of care (SoC) costs were found non-differential.

(trade secret)

The estimated incremental cost–utility ratio (ICUR) was:

- 14,000 from the NFZ's perspective;
- (trade secret)

With the aforementioned ICUR values in mind, the threshold net selling price of the drug is:

- from the NFZ's perspective:
    - PLN 1,149.00 for a pack containing 30 tablets;
    - PLN 536.20 for a pack of tablets;
- from the joint perspective:
    - PLN 1,144.37 for a pack containing 30 tablets;
    - PLN 534.04 for a pack of tablets;

Deterministic and probabilistic analyses are presented. The deterministic analysis considered parameters such as (trade secret)

Limitations

While interpreting the aforementioned estimates, it should be borne in mind that the analysis was based on the results of studies, meaning that their limitations also apply to economic analysis.

Indication whether the circumstances referred to in Art. 13 sec. of the Act of 12 May 2011 on the reimbursement of drugs, foodstuffs intended for particular nutritional uses and medical devices (Journal of Laws of 2019, item 784 as amended)

If the applicant's clinical analysis does not include randomised clinical trials proving the superiority of the drug over health technologies already reimbursed in a particular indication, the official sales price of the drug must be calculated in such a way that the cost of use of the drug whose reimbursement is applied for is not higher than the cost of health technology with the most favourable ratio of obtained health outcome to the cost of obtaining them.

The applicant's clinical analysis includes a randomised clinical trial pointing to the superiority of dapagliflozin over standard therapy, which means that 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 are absent.

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

The health system impact assessment has two major parts.

First, a payer budget impact analysis allows estimating the potential expenses associated with public funding 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 resources to treat a given health problem or is associated with savings in the payer's budget.

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

The assessment of health system impact in the second part answers the question of how the decision to fund the new therapy may affect the organisation of service delivery (particularly in the context of adjusting to the requirements of delivering the new therapy) and the availability of other healthcare services.

In case of the decision to reimburse dapagliflozin (Farxiga) in the indication: chronic heart failure in adult patients with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs)

and beta blockers and, if indicated, mineralocorticoid receptor antagonists, budget impact analysis was performed for a period of 4 years. The analysis was conducted from both the payer's perspective and a joint one (NFZ + patient). The applicant assumed that the following will be added to dapagliflozin treatment in subsequent years:

(trade secret)

The following cost categories were included in the analysis:

- dapagliflozin costs;
- standard treatment costs;
- diabetes comorbidity costs;
- costs of cardiovascular events and treatment of adverse events.

If the decision is made to reimburse Forxiga in the requested indication, public payer's expenses to be incurred in the target population (trade secret)

- from the NFZ's perspective:
    - (trade secret)
- from the joint perspective:
    - (trade secret)

Limitations

The uncertainty of the presented estimates is affected by the following aspects:

- some of the parameters used by the applicant to estimate the target population may raise doubts. The percentage of patients willing to pay extra for Forxiga was adopted based on a price elasticity survey carried out on a group of diabetes specialists and patients suffering from diabetes, which is a limitation in itself and involves estimation uncertainty. Both this parameter and other relevant parameters (concerning the estimation of the population covered by the application) were not tested in sensitivity analysis;
- if the reimbursement decision is positive, the specified annual supply volume is insufficient for both drug presentations.

Comments on the proposed risk-sharing instrument

(trade secret)

Comments on the drug programme

Not applicable.

Discussion of the solutions proposed in the rationalisation analysis

The rationalisation analysis aims to identify a mechanism whose introduction 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 reimbursement of the health technology named in the application.

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

(trade secret)

Discussion of recommendations in relation to the evaluated technology

A total of 6 documents being national recommendations and recommendations of international and foreign scientific societies were identified:

- European European Society of Cardiology (ESC) 2016;
- Polish Cardiac Society (PTOK) 2017;
- National Institute for Health and Care Excellence (NICE) 2018a;
- American College of Cardiology/ American Heart Association (ACC/AHA) 2017;
- Scottish Intercollegiate Guidelines Network (SIGN) 2016;
- Canadian Cardiovascular Society (CCS) 2017.

Most of the identified guidelines for heart failure treatment (especially those focusing on the treatment of heart failure with reduced ejection fraction) recommend the use of beta blockers with ACEIs or, in the case of ACEI intolerance, ARBs as well as MRAs. If the aforementioned therapy is ineffective, ARNIs may replace ACEIs and ivabradine or resynchronisation therapy may be added.

The ESC 2017 guidelines point to the possibility of the combined use of these therapies. If the used therapy is still ineffective, digoxin, a combination of hydralazine and isosorbide dinitrate, mechanical left ventricular assist support, or heart transplantation should be considered.

The described clinical guidelines do not cover the use of dapagliflozin, but it should be pointed out that the date of publication of the guidelines predates the publication of the DAPA-HF trial results.

One NICE 2021 recommendation in favour of reimbursement was identified (ongoing). The use of dapagliflozin under NHS was initially recommended. The most probable ICER values for dapagliflozin compared to all appropriate comparators are within the NICE-acceptable range.

(trade secret)

Basis for the recommendation

The recommendation was prepared under the order of the Minister of Health of 17 December 2020 (reference numbers: PLR.4500.1309.2020; PLR.4500.1310.2020) regarding the preparation of the President's recommendation on the reimbursement of the Farxiga drug (dapagliflozin) in the following indication: chronic heart failure in adult patients with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists 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 (Journal of Laws of 2020, item 357, as amended) and following Transparency Council Opinion No. 19/2021 of 15 February 2021 on the assessment of the Farxiga drug (dapagliflozin) in the following indication: chronic heart failure in adult patients with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists

PRESIDENT

dr n. med. Roman Topór-Mądry

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References

1. Transparency Council Opinion No. 19/2021 of 15 February 2021 on the assessment of the Farxiga drug (dapagliflozin) in the following indication: chronic heart failure in adult patients with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart

Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists

2. Report No. OT.4330.21.2020. Application concerning the reimbursement of the Farxiga drug (dapagliflozin) in the following indication: chronic heart failure in adult patients with reduced left ventricular ejection fraction (LVEF≤40%) and persistent symptoms of the disease in New York Heart Association classes II–IV despite the therapy based on ACEis (or ARBs) and beta blockers and, if indicated, mineralocorticoid receptor antagonists. Verification analysis.