Recommendation No. 128/2021

of 25 November 2021

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

on the assessment of Gardasil, vaccine against human papillomavirus (HPV) [types 6, 11, 16, 18], in the following indication: prevention of: premalignant lesions of genital organs (uterine cervix, vulva and vagina), premalignant lesions of the anus, cervical cancer and anal cancer causally related to infection with certain oncogenic human papillomavirus (HPV) types; genital warts (condylomata acuminata) causally related to infection with specific HPV types in persons aged 9 and older

The President of the Agency recommends the reimbursement of Gardasil, vaccine against human papillomavirus (HPV) [types 6, 11, 16, 18], in the following indication: prevention of: premalignant lesions of genital organs (uterine cervix, vulva and vagina), premalignant lesions of the anus, cervical cancer and anal cancer causally related to infection with certain oncogenic human papillomavirus (HPV) types; genital warts (condylomata acuminata) causally related to infection with specific HPV types in persons aged 9 and older, [information protected as a trade secret] **provided that [information protected as a trade secret]**

Grounds for the recommendation

It was taken into account that according to Polish and foreign clinical recommendations, HPV vaccination is an important element of primary prevention against cervical cancer and other diseases. Moreover, HPV vaccination is included in the 2022 recommended vaccination list in Poland and in the National Oncological Strategy recommending their implementation as part of health prevention programmes. It should also be pointed out that [information protected as a trade secret]

Numerous clinical trials and observational studies confirm the efficacy of HPV vaccines in preventing HPV infection events, including their efficacy in clinically relevant endpoints. At the same time, even though the scientific evidence presented by the applicant confirms the efficacy of Gardasil in the population of girls aged 9 years and above and young women, there are no data comparing its efficacy in relation to the vaccine currently reimbursed in Poland, i.e. Cervarix. Available RCTs directly

comparing Gardasil and Cervarix evaluate only the safety and immunogenicity of these vaccines.

Due to failure to provide an electronic model to ensure full verification of the data, the estimates of the economic analysis are subject to excessively large uncertainty to accept its conclusions. [information protected as a trade secret]

The results of the applicant's budget impact analysis indicate [information protected as a trade secret]

Taking into account the above arguments as well as the proposed price of the proposed technology, it seems reasonable to finance Gardasil [information protected as a trade secret]

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:

- Gardasil, human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed), suspension for injection, 1, pre-filled syringe 0.5 ml + 2 needles, GTIN code: 00191778016130, net sales price: [information protected as a trade secret]

Proposed payment and dispensing category: [information protected as a trade secret] on prescription in the indication specified by a clinical condition, [information protected as a trade secret]

Health problem

[information protected as a trade secret]

Human papillomavirus (HPV) is a non-enveloped DNA virus. There are more than 100 types of HPV that lead to infection in the skin and mucous membranes.

Approximately 40 virus types have been identified that are responsible for genitourinary infections in men and women, including:

- highly oncogenic types - 8 types (16, 18, 31, 33, 35, 45, 56 and 58) are of particular importance in the European population, with the first two types - 16 and 18 - accounting for 73% of all cases of cervical cancer (CC). In addition to developing cervical cancer, infections with these viruses can also lead to other cancers: anal, penile, vulvar, oral and laryngeal;
- low-oncogenic types - particularly types 6 and 11, which are responsible for the formation of genitourinary warts.

According to the Polish National Cancer Registry data from 2018, cervical cancer was the seventh most common malignancy among women in Poland.

The annual number of new cervical cancer cases in Poland in 2018 was 3,220 and the annual number of deaths was 1,947.

Alternative health technology

Taking into account clinical guidelines and currently publicly-funded technologies, comparators for the proposed technology are:

1. lack of primary prevention interventions;
2. bivalent vaccine - Cervarix.

It should be noted that in addition to the selected comparators, a 9-valent vaccine, Gardasil 9, was among the optional technologies identified by the experts.

Description of the proposed intervention

Gardasil is an adjuvant-containing, non-infectious, recombinant, quadrivalent vaccine derived from highly purified virus-like particles (VLP) of the L1 major capsid protein of HPV types 6, 11, 16, and 18.

According to the SmPC, Gardasil 9 is indicated for active immunisation of individuals from the age of 9 years against the following HPV diseases:

- premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types.

- genital warts (Condyloma acuminata) caused by specific HPV types.

The proposed indication is consistent with the registration indication.

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 clinical analysis included 13 primary studies on:

- efficacy:
    - 4vHPV (Gardasil) vs no vaccination: P007, P013, P015, P019, V501-041, Yoshikawa 2013;
- safety:
    - 4vHPV (Gardasil) vs no vaccination: P007, P013, P015, P019, P023, P046, V501-041, NCT01489527, Yoshikawa 2013;
    - 4vHPV (Gardasil) vs 2vHPV (Cervarix): NCT00956553, NCT00423046 (Einstein 2009, Einstein 2011, Einstein 2014a, Einstein 2014b), NCT01462357 (Leung 2015, Leung 2018), Nelson 2013;
- immunogenicity:
    - 4vHPV (Gardasil) vs no vaccination: P007, P023, P046;
    - 4vHPV (Gardasil) vs 2vHPV (Cervarix): NCT01462357 (Leung 2015, Leung 2018), NCT00956553, NCT00423046 (Einstein 2009, Einstein 2011, Einstein 2014a, Einstein 2014b).

Furthermore, 22 studies on vaccination with the quadrivalent HPV vaccine were included in a population of girls and women in an actual clinical practice setting:

- HPV vaccine efficacy assessment: Guo 2015 (USA); Wendland 2021 (Brazil);
- assessment of vaccine efficacy in relation to the prevention of cervical diseases: Baldur-Felskov 2014 (Denmark); Herweijer 2016 (Sweden); Innes 2020 (New Zealand); Rodriguez 2020 (USA); Silverberg 2018 (USA); Smith 2015 (Canada); Righolt 2019 (Canada), Kjaer 2021 (Denmark);
- assessment of vaccination efficacy in relation to the prevention of genital warts: Baandrup 2013 (Denmark); Blomberg 2015 (Denmark); Navarro-Illana 2017 (Spain); Petráš 2015 (Czech Republic);

- assessment of efficacy in relation to the prevention of condylomata acuminata: Lamb 2017 (Sweden);
- safety assessment of 4vHPV vaccination: Bonaldo 2019 (Italy); Cramon 2017 (Denmark); Kim 2020 (Korea); Mauro 2019 (Brazil); Phillips 2020 (Australia); Scheller 2015 (Denmark, Sweden); Šubelj 2016 (Slovenia).

Conclusions of 4 systematic reviews were also presented:

- Aldakak 2021 - review to determine gender differences in the immunogenicity of the 4-valent HPV vaccine (Gardasil), mainly including randomised trials;
- Bergman 2019 - review on the efficacy and safety of available HPV vaccines, including Gardasil, in girls/women and boys/men, including RCTs only;
- Gonçalves 2014 - review on the efficacy and safety of available HPV vaccines, including Gardasil, in girls/women, including RCTs only;
- Ogawa 2017 - review on the efficacy and safety of available HPV vaccines including Gardasil in a population of healthy young women.

The primary studies mainly evaluated:

- incidence of HPV infection, cervical or external genital disease;
- immunogenicity (HPV neutralising antibody titers);
- adverse events.

Reliability assessment of RCTs was performed using the Cochrane Collaboration's risk-of-bias assessment tool. Low risk of bias in all domains evaluated applied to:

- among 9 RCTs comparing 4vHPV vs no vaccination: studies P007, P013, P015, P019, V501-041, Yoshikawa 2013;
- among 4 RCTs comparing 4vHPV vs 2vHPV: studies NCT00423046 (Einstein), NCT00956553, NCT01462357 (Leung).

The remaining RCTs included in the clinical analysis varied in quality, with low or unclear risk being noted across domains.

Among the systematic reviews included in the clinical analysis, the Aldakak 2021 and Bergman 2019 reviews were of high quality, according to the AMSTAR 2 scale, while the Gonçalves 2014 and Ogawa 2017 reviews were of moderate quality.

Efficacy

Gardasil vs no vaccination

In RCTs comparing Gardasil with placebo/no HPV vaccination, the following issues were identified:

- a statistically significantly lower risk of cervical disease of any grade associated with infection: HPV-6/11/16/18 (statistically significant difference in four out of six studies and in the meta-analysis of the results of two studies), HPV-6, HPV 18;
- a statistically significantly lower risk of the following endpoints: CIN1+ lesions associated with HPV 6/11/16/18 infection, CIN2+ lesions associated with HPV 6/11/16/18 infection, CIN3+ lesions associated with HPV 6/11/16/18 infection, AIS lesions associated with HPV 6/11/16/18 infection.

For the endpoint of high-grade cervical disease (CIN2, CIN3, AIS lesions, cervical cancer) associated with HPV 6/11/16/18 infection, the difference in favour of the group taking Gardasil reached statistical significance in one out of three studies.

There were no statistically significant differences in the risk of cervical disease of any grade associated with HPV-11 infection (one study).

Gardasil vs Cervarix

There are no data on the efficacy of Gardasil in relation to the only currently reimbursed vaccine in Poland, i.e. Cervarix.

Effectiveness

Guo 2015 (USA) and Wendland 2021 (Brazil) studies demonstrated the efficacy of the 4vHPV vaccine in respect of HPV vaccine strains. In the Guo 2015 study, vaccinated women had a significantly lower incidence of vaccinated HPV types than unvaccinated women (7.4% vs 17.1%, incidence rate 0.43, 95% CI: 0.21-0.88).

All six studies identified [Baldur-Felskov 2014 (Denmark); Herweijer 2016 (Sweden); Innes 2020 (New Zealand); Righolt 2019 (Canada); Rodriguez 2020 (USA); Silverberg 2018 (USA); Smith 2015 (Canada)] revealed that the incidence of cervical lesions was significantly reduced with 4vHPV vaccination.

Four studies [Baandrup 2013 (Denmark); Blomberg 2015 (Denmark); Navarro-Illana 2017 (Spain); Petráš 2015 (Czech Republic)] pointed to a high efficacy of 4vHPV vaccination in reducing the incidence of genital warts. In the 2015 Petráš Czech study, the incidence of warts was reduced by 90.6% (80.1-95.6%) in vaccinated women at least one year after completion of 4vHPV vaccination compared to unvaccinated women.

The 2017 Lamb study (Sweden) showed that a two-dose schedule of 4vHPV vaccine with a 4-7 month interval between the first and second dose could be as effective against warts in girls and women starting vaccination under 20 years of age as a three-dose schedule.

Safety

Gardasil vs no vaccination

In the P019 study comprising women aged 24-45, there was a higher risk of death in the Gardasil group compared with the placebo/no HPV vaccination group for a 48-month follow-up period - the difference was statistically significant for the RD parameter, but did not reach statistical significance for the OR parameter.

In other RCTs including both girls and women up to 26 years of age (P046: 9-26 years, Yoshikawa 2013: 18-26 years, P013: 16-24 years, P015: 15-26 years) as well as a slightly older group (V501-041: women aged 20-45 years), there were no significant differences in the number of deaths between groups for follow-up periods of 15 days, 30-36 months, 90 months depending on the study.

In RCTs comparing Gardasil with placebo/no HPV vaccination, both in studies with a short follow-up period (14-15 days) and in studies with a long follow-up period (30-48 months), there were no statistically significant differences in the risk of: treatment discontinuation due to adverse events, treatment discontinuation due to adverse effects, treatment discontinuation due to serious adverse events, treatment discontinuation due to serious adverse effects.

Gardasil vs Cervarix

In the RCTs for the comparison of Gardasil vs Cervarix, during the 7-day follow-up period, there was a statistically significantly lower risk of injection site pain, severe injection site pain, injection site swelling (statistically significant difference in two of the three studies and in the meta-analysis), grade 3 headache (statistically significant difference in one of the three studies), gastrointestinal disorders (statistically significant difference in one of the three studies), grade 3 joint pain (statistically significant difference in one of the three studies and in the meta-analysis), myalgia (statistically significant difference in one of the three studies and in the meta-analysis), rash (statistically significant difference in one of the three studies and in the meta-analysis), redness, urticaria. In addition, the result of the meta-analysis showed a statistically significantly lower risk of headache (in individual studies, the differences did not reach statistical significance).

There were no statistically significant differences in the incidence of severe swelling at the injection site, fever, grade 3 gastrointestinal upset, grade 3 myalgia, rash, grade 3 rash.

Limitations

The main limitation of the clinical analysis presented here is that it does not cover the entire population in question, i.e. people aged 9 and over and focuses only on girls and women. Furthermore, given the lack of primary studies comparing HPV vaccine efficacy, a significant limitation of the analysis is the failure to perform an indirect comparison for Gardasil and Cervarix.

Proposed risk-sharing scheme
[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.

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 / 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 the use of this assessment to choose the therapy related to potentially the best outcome.

As part of the cost-effectiveness assessment, cost-utility analysis (CUA) was performed over a lifetime horizon (100 years) from the public payer perspective - the entity obliged to finance services from public funds, i.e. the National Health Fund (NHF) and from the joint perspective of the payer and the patient.

The analysis includes costs of:

- vaccinations,
- screenings for cervical cancer,
- treatment of diseases related to HPV infection.

Gardasil vs Cervarix, Gardasil vs no vaccination [information protected as a trade secret]

Limitations

The economic analysis has many limitations; therefore, the estimated ICUR values for the Gardasil vs no vaccination/Cervarix comparison have low reliability.

First of all, no electronic document was attached, so it was not possible to verify the structural correctness of the applicant's model, the model inputs or the results obtained. Without the economic model, it is not possible to verify the calculations made as part of the economic analysis or to modify any of the parameters used in these calculations to check the impact of the assumptions made on

the results.

In addition, the chosen analytical technique – CUA – is not sufficiently justified given the lack of presentation of precise sources of efficacy parameters in AEs and the results of the clinical analysis indicating that Gardasil is superior to Cervarix only in terms of short-term safety.

Agency's own calculations

In the absence of an electronic document, it was not possible to verify the structural correctness of the applicant's model, the model input data or the resulting calculations.

A cost breakdown of HPV vaccines available in Poland was prepared as part of the Agency's own calculations [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.

In the considered case, the circumstances referred to in Art. 13 sec. 3 of the Reimbursement Act do not arise.

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.

The results of the applicant's budget impact analysis are presented over a two-year horizon. The analysis was conducted from the perspective of public payer (NHF) and joint perspective.

The analysis considered [information protected as a trade secret]

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

The results of the basic analysis indicate that the reimbursement of Gardasil in the indication in question will involve [information protected as a trade secret] This is due to the assumption that in the first year of analysis, the following number of people will be vaccinated [information protected as a trade secret]

Limitations

The main limitations of the analysis arise from uncertainties in the proportion of the people vaccinated, the size of the Gardasil vaccine market share and the lack of inclusion of the male population in the estimates.

The analyses did not provide evidence to determine whether there was a relationship between influenza vaccination propensity and HPV vaccination (influenza vaccination data were included in the estimates).

Agency's own calculations

Results were estimated for an alternative option including: age restriction according to experts' opinions, male population and higher vaccination rates compared to the basic variant of the analysis.

The adoption of the above assumptions implied [information protected as a trade secret]

It should also be noted that from the NHF perspective, differential costs of vaccination will occur in the 14-year-old population - Gardasil in this group is recommended in a three-dose schedule, while Cervarix in a two-dose schedule. In 2022, maximum incremental costs borne by the National Health Fund (assuming 100% market share of Gardasil and 100% vaccination rate in the group of 14-year-old boys and girls) may amount to [information protected as a trade secret]

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

Comments on the drug programme

Not applicable.

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. [information protected as a trade secret]

[information protected as a trade secret]

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

Four Polish recommendations were found:

- 2022 Immunisation Programme,
- Interim Recommendations of the Polish Society of Gynaecologists and Obstetricians and the Polish Society of Colposcopy and Cervical Pathophysiology for secondary prevention of cervical cancer during the SARS-CoV-2 pandemic of 2021,
- position of the Polish Society of Colposcopy and Cervical Pathophysiology Board of 2018,
- 2017 recommendations of the Polish Society of Oncological Gynaecology,

and 11 foreign recommendations:

- European Federation for Colposcopy – European Society of Gynaecological Oncology (EFC –

ESGO) of 2019 and 2020,

- European Cancer Organisation (ECO) of 2020,
- European Centre for Disease Prevention and Control (ECDC) of 2020,
- World Health Organization (WHO) of 2017 and WHO's 2020 report on a global strategy for future years in the prevention of cervical cancer,
- Advisory Committee on Immunization Practices (ACIP) of 2019,
- American College of Obstetricians and Gynecologists (ACOG) of 2020.
- American Society of Clinical Oncology (ASCO) of 2017,
- American Cancer Society (ACS) of 2020,
- Advisory Committee Statement-National Advisory Committee on Immunization (ACS-NACI) of 2017,
- Italian Society of Colposcopy–Cervico Vaginal Pathology (SICPCV) of 2020,
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) of 2019

HPV vaccination is included in the list of recommended vaccinations for 2022 in Poland, but not financed under the Immunisation Programme. The recommendations include specifically people aged 9 and over for immunisation against diseases caused by specific types of HPV.

Vaccination is recommended as part of the National Cancer Strategy and recommended as part of preventive health programmes. According to the Polish Society of Colposcopy and Cervical Pathophysiology of 2018 and the Polish Society of Gynecological Oncology of 2017, HPV vaccination is a recommended element of primary prevention, even without reference to gender or age.

All international guidelines (EFC – ESGO 2019 2020, ECO 2020, ECDC 2020, WHO 2017, ACIP 2019, ACOG 2020, ASCO 2017, ACS 2020, ACS-NACI 2017, SICPCV 2020, RANZCOG 2019) also indicate HPV vaccination as an important element of prevention against, among others, cervical cancer. The recommendations that were identified favour vaccination as early as possible because of optimal immune response – in both men and women.

Reimbursement recommendations

There was 1 positive recommendation for Gardasil/Gardasil 9 (PTAC), 4 current positive recommendations for Cervarix (HAS, HCN, PBAC, NIPH), 2 recommendations without indication of a specific vaccine type (GHCS & FJC and HCN) and 1 recommendation to replace bivalent and quadrivalent vaccines with a nine-valent vaccine (HIQA).

In France, Gardasil has been funded since 2007, currently 100% co-paid, and is used for the prevention of infections and lesions caused by certain oncogenic types of human papillomavirus (HPV) in girls aged 11-14 and women before the age of 20 years. Concurrently, Gardasil 9 is preferentially recommended as it provides protection against nine HPV genotypes (whereas Gardasil is quadrivalent and Cervarix is bivalent).

In the Netherlands, Gardasil (along with Cervarix) has been reimbursed for girls since 2010. In 2019, the HCN recommended that children of both sexes should be vaccinated around 9 years of age (without indicating specific vaccines). In addition, a supplementary vaccination programme was to be prepared for those under 26 years of age.

In 2008, the Irish HIQA recommended Cervarix and Gardasil vaccines to be reimbursed for girls aged 12; in addition, in 2018, it recommended Gardasil 9 for use in children of both sexes.

In 2006, the Australian PBAC recommended Gardasil to be reimbursed for girls aged 12-18. By contrast, in 2011, it recommended the national vaccination programme to be expanded to include the quadrivalent Gardasil vaccine in boys aged 12-13, as well as in boys 2 years older (for a period of

2 years). The 2019 PBAC recommendation advocates Gardasil 9 in a two-dose schedule for children aged 12-13 as part of school vaccinations. The vaccine is expected to replace the current 3-dose 4vHPV vaccination schedule. The PBAC notes limitations in clinical evidence, including the lack of a randomised controlled trial directly comparing the 2-dose 9vHPV vaccine schedule with the 3-dose 4vHPV vaccine schedule in the studied population (the study involved adult women). The ICER for a 3-dose 9vHPV versus 3-dose 4vHPV vaccination schedule was found to be acceptable.

Recommendations from the New Zealand PHARMAC in 2013 recommended Gardasil for use in boys aged 11-19, in homosexual men aged 9-26 and in girls aged 11 and older. According to the Committee, despite its efficacy, vaccination with Gardasil is not cost-effective in boys because they benefit from herd immunity. According to the 2016 recommendations, Gardasil will be replaced by a 9-valent vaccine (Gardasil 9) starting in 2017.

In contrast, the German GHCS & FJC does not identify a specific vaccine in their recommendations; the 2018 recommendations include the administration of 3 doses of HPV vaccine in children of both sexes aged 9 to 14 under health insurance.

In Norway, Cervarix has been funded in girls (from 2009) and boys (from 2018) as part of the vaccination programme since 2008.

According to the information provided by the applicant, Gardasil is funded in [information protected as a trade secret] EU and EFTA countries (per 31 indicated). [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 6 September 2021 of the Minister of Health (ref. no.: PLR.4500.2857.2021.3.RBO) regarding the preparation of the President's recommendation on the assessment of Gardasil, vaccine against human papillomavirus (HPV) [types 6, 11, 16, 18], for the following indication: prevention of: premalignant lesions of genital organs (uterine cervix, vulva and vagina), premalignant lesions of the anus, cervical cancer and anal cancer causally related to infection with certain oncogenic human papillomavirus (HPV) types; genital warts (condylomata acuminata) causally related to infection with specific HPV types in persons aged 9 and older 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. 121/2021 of 18 October 2021 on the assessment of Gardasil, vaccine against human papillomavirus (HPV) [types 6, 11, 16, 18], for the following indication: prevention of: premalignant lesions of genital organs (uterine cervix, vulva and vagina), premalignant lesions of the anus, cervical cancer and anal cancer causally related to infection with certain oncogenic human papillomavirus (HPV) types; genital warts (condylomata acuminata) causally related to infection with specific HPV types in persons aged 9 and older

References

1. Position of the Transparency Council No. 128/2021 of 22 November 2021 on the assessment of Gardasil, vaccine against human papillomavirus (HPV) [types 6, 11, 16, 18], for the following indication: prevention of: premalignant lesions of genital organs (uterine cervix, vulva and vagina), premalignant lesions of the anus, cervical cancer and anal cancer causally related to infection with certain oncogenic human papillomavirus (HPV) types; genital warts (condylomata acuminata) causally related to infection with specific HPV types in persons aged 9 and older
2. Report No. OT.4230.19.2021 Application for the reimbursement of Gardasil, vaccine against human papillomavirus (HPV) [types 6, 11, 16, 18], for the following indication: prevention of: premalignant lesions of genital organs (uterine cervix, vulva and vagina), premalignant lesions of the anus, cervical cancer and anal cancer causally related to infection with certain oncogenic human papillomavirus (HPV) types; genital warts (condylomata acuminata) causally related to infection with specific HPV types in persons aged 9 and older