SUMMARY OF DECISIONS FROM THE SPANISH INTERMINISTERIAL MEDICINAL PRODUCTS PRICING COMMITTEE (CIPM)

SESSION 208 OF DECEMBER 17TH, 2020

December 17th, 2020

INFORMATIVE NOTE FROM THE SPANISH INTERMINISTERIAL MEDICINAL PRODUCTS PRINCING COMMITTEE MEETING

SESSION 208 OF DECEMBER 17th, 2020

For information purposes, this note summarises the **main agreements** established by the Spanish Interministerial Medicinal Products Pricing Committee (CIPM), a collegial body competent in setting the maximum industrial price, gathered on December 17th, 2020.

It is specified that these agreements are not definitive since, prior to the Resolution by the Directorate-General for Basic Portfolio of Services of the National Health System and Pharmacy, the processing of allegations to the Project Resolution is at the disposition of the company, according to the administrative procedure.

The agreements taken in this Committee of September 2020 will not be effective until the corresponding final Resolution is issued by the Directorate-General for Basic Portfolio of Services of the National Health System and Pharmacy and the changes generated by these agreements are included in the corresponding billing Nomenclator.

The agreements differ into two **blocks**: agreements with pricing and reimbursement (approvals) and rejected agreements.

Each block is divided into the following **sections**:

A. New medicinal products: This section includes the agreements related to the inclusion or non-inclusion in the pharmaceutical provision of the National Health System (NHS) of **medicines with new active ingredients or combinations (A.1) and other medicines (A.2)** (this subsection includes, for example, the first generics, first biosimilars and first copies, among others).

B. New indications: This section includes the agreements regarding the inclusion or non-inclusion in the pharmaceutical provision of the NHS of **new indications of medicines that are already included in the pharmaceutical provision of the NHS.**

C. Modifications to the pharmaceutical offering: This section includes the agreements related to alterations in the offer, i.e., to the **modification of reimbursement and price conditions** (price raises or reductions, conditions of prescription and dispensation, exclusion of the provision) of medicines included in the pharmaceutical provision of the NHS.

D. Allegations: This section includes the agreements related to the records (may be new drugs, new indications or alterations of the offer) that have obtained an agreement of acceptance or non-acceptance of the allegations presented by the medicine's laboratory holder object of record.

In case that the medicines' laboratory holders included in sections A (new medicinal products), B (new indications) and C (modifications to the pharmaceutical offering) do not present allegations and accept the draft resolution or submit the allegations and these are accepted, a reimbursement resolution will be issued.

In case that the medicines' laboratory holders included in sections A (new medicinal products), B (new indications) and C (modifications to the pharmaceutical offering) present allegations and these are not accepted, a specific resolution of non-reimbursement will be issued.

It should be noted that in sections A (new medicinal products), B (new indications) and D (allegations) are included, both in the text of the agreement and in the table that is included in record, the reasons for reimbursement / non-reimbursement, these being those established in article 92 of Royal Legislative Decree 1/2015, of July 24th, where the revised text of the Law on guarantees and rational use of medicines and medical devices through (*Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios*) is approved and by which medicinal products are financed:

Article 92

a) *Severity, duration, and sequelae of the different pathologies for which they are indicated.*
b) *Specific needs of certain groups.*
c) *Therapeutic and social value of the medicinal product and its incremental clinical benefit, taking into account its cost-effectiveness ratio.*
d) *Rationalisation of public expenditure for pharmaceutical provision and budget impact in the National Health System.*
e) *Existence of medicinal products or other therapeutic alternatives for the same conditions at a lower price or lower treatment cost.*
f) *Degree of innovation of the medicinal product.*

In section C (modifications to the pharmaceutical offering) the criteria for decision-making are those established in articles 93 and 96 of the above-mentioned Law.

1. P&R APPROVALS

A. NEW MEDICINAL PRODUCTS

A.1. NEW MEDICINAL PRODUCTS

○ ERLEADA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
JANSSEN CILAG SA	ERLEADA 60 MG	112 film-coated tablets	724602	3173,33	a) y c)
JANSSEN CILAG SA	ERLEADA 60 MG	112 film-coated tablets	724602	3173,33	a) y c)

Active substance: L02BB05- Apalutamide

Therapeutic indication:

Erleada is indicated in adult men for the treatment of non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.

Erleada is indicated in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- **Financing** the medicine for the treatment of high-risk non-metastatic castration resistant prostate cancer according to the following **clinical criteria** that patients must meet for its use:
  - ✓ High risk of metastasis (PSA Doubling Time (PSADT) < 6 months.
  - ✓ PSA levels ≥ 2ng/ml, with castrate testosterone levels < 50ng/dl or 1,7 nmol/l during the treatment with LHRH agonists or bilateral orchiectomy).
  - ✓ No evidence PET/CT with choline No previous or present evidence of metastatic disease, recommended diagnosis by choline PET-CT, and especially by PSMA PET/CT.
  - ✓ Good performance status (ECOG 0-1).
  - ✓ Geriatric assessment of potentially frail patients.
  - ✓ Patient comorbidities analysis.

- ✓ Consideration of concomitant medication.

- **Financing** the medicine for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT) in adult men who cannot tolerate or are not candidates for chemotherapy with Docetaxel.
- Enzalutamide, apalutamide and darolutamide should not be used sequentially after progression to one of them.
- Establishment for this medicine of **special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, without the need for a visa, to patients not hospitalised in the Pharmacy Services of Hospitals.
- **Annual review of sales** and prices now set, to ensure that they are within the legally established parameters, and if not, proceed to their adaptation through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ TAKHZYRO

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
TAKEDA FARMACEUTICA ESPAÑA SA	TAKHZYRO 300 MG	Solution for injection 1 vial of 2 ml	724748	14.166	a) y c)
TAKEDA FARMACEUTICA ESPAÑA SA	TAKHZYRO 300 MG	Solution for injection 1 pre-filled syringe of 2 ml	729166	14.166	a) y c)

Active substance: B06AC05 – Lanadelumab.

Therapeutic indication:

Takhzyro is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older.

Prescription and dispensation conditions: Medical prescription. Hospital use.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.

- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ LUXTURNA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
NOVARTIS FARMACEUTICA SA	LUXTURNA 5 x 10^{12} VECTOR GENOMES/ ML	1 vial 0,5 ml (concentre) + 2 vials 1,7 ml (solvent)	724967	345.000	a) y c)

Active substance: S01XA27 - Voretigene neparvovec

Therapeutic indication:

Luxturna is indicated for the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.

Prescription and dispensation conditions: Medical prescription. Hospital use.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- **Propose financing** to the General Directorate, through a payment agreement for the results in the following conditions:

  Clinical criteria that patients must meet for its use:

  Inclusion criteria

  - ✓ Clinical diagnosis of retinal dystrophy (including visual acuity measurements, visual field, fundus of the eye, electrophysiological tests, colour test, autofluorescence and optical coherence tomography).
  - ✓ Presence of biallelic RPE65 mutation by genetic analysis. The mutations should be classified as pathogenic or probably pathogenic variants or probably pathogenic.
  - ✓ Age older than 4 years.
  - ✓ Visual acuity equal to or less than 20/60 or visual field of less than 20 degrees in any meridian measured by isopter III4e or equivalent (both eyes).
  - ✓ Sufficient viable retinal cells (central retinal thickness ≥ 100 µm in posterior pole, as determined by optical coherence tomography (OCT) and/or ophthalmoscopy).

Exclusion criteria

- ✓ Patients who have been treated with gene therapies or who have previously participated in gene therapy clinical trials.
- ✓ Presence of ocular conditions or systemic diseases that may interfere with study interpretation.
- ✓ Intraocular surgery within the previous 6 months
- ✓ Use of high-dose retinoid compounds or precursors in the previous 18 months.
- ✓ Pregnant women and patients who are not using effective contraceptive methods within 4 months of vector administration.

- The determination of individual compliance with the payment conditions will be made through a **Monitoring Committee in each Autonomous Community** that will be established between the health administrations and the offering / supplier laboratory. This information will be transferred to the General Directorate of Common Portfolio of Services of the NHS and Pharmacy in order to determine the need for a price review.
- The General Directorate of Common Portfolio of Services of the NHS and Pharmacy will prepare a **pharmacoclinical protocol** that must be completed throughout the NHS, through VALTERMED, which contains both the criteria for starting, monitoring and discontinuing treatment as well as the variables to be recorded to determine the results of the use of this medicine in clinical practice.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ LORVIQUA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
PFIZER. SL	LORVIQUA 100 MG	30 film-coated tablets	725704	5.230	a) y c)
PFIZER. SL	LORVIQUA 25 MG	90 film-coated tablets	727072	5.230	a) y c)

Active substance: L01XE44- Lorlatinib

Therapeutic indication:

Lorviqua as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after: alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or crizotinib and at least one other ALK TKI.

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- Establishment for this medicine of **special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, without the need for a visa, to patients not hospitalised in the Pharmacy Services of Hospitals.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ NUBEQA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
BAYER HISPANIA SL	NUBEQA 300 MG	112 film-coated tablets	728305	3.173,33	a) y c)

Active substance: L02BB06- Darolutamide

Therapeutic indication:

NUBEQA is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease (see section 5.1 of the SmPC).

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- **Financing** the medicine for the treatment of high-risk non-metastatic castration resistant prostate cancer according to the following **clinical criteria** that patients must meet for its use:
  - ✓ High risk of metastasis (PSA Doubling Time (PSADT) < 6 months.

- ✓ PSA levels ≥ 2ng/ml, with castrate testosterone levels < 50ng/dl or 1,7 nmol/l during the treatment with LHRH agonists or bilateral orchiectomy).
- ✓ No evidence PET/CT with choline No previous or present evidence of metastatic disease, recommended diagnosis by choline PET-CT, and especially by PSMA PET/CT.
- ✓ Good performance status (ECOG 0-1).
- ✓ Geriatric assessment of potentially frail patients.
- ✓ Patient comorbidities analysis.
- ✓ Consideration of concomitant medication.

- Establishment for this medicine of **special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, without the need for a visa, to patients not hospitalised in the Pharmacy Services of Hospitals.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

A.2 OTHER MEDICINAL PRODUCTS

○ PIOGLITAZONE/METFORMIN ARISTO

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
ARISTO PHARMA IBERICA SL	PIOGLITAZONA/METFORMIN15 MG/850MG EFG	56 film-coated tablets	727796	20,65	d)

Active substance: A10BD05 Metformin and poglitazone

Therapeutic indication:

This medicinal product is indicated as a second line treatment for adult patients with type 2 diabetes mellitus, particularly overweight patients, who do not achieve sufficient glycaemic control with the maximum tolerated dose of oral metformin monotherapy. After initiation of treatment with pioglitazone, patients should be reviewed after 3 to 6 months to assess adequacy of response to treatment (e.g., reduction in HbA1c). In patients who fail to show an adequate response, pioglitazone should be discontinued. In light of potential risks with prolonged therapy, physicians (prescribers) should confirm at subsequent routine reviews that the benefit of pioglitazone is maintained.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.

○ FOSCARNET

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
FRESENIUS KABI ESPAÑA, S.A.U..	FOSCARNET KABI 24 MG/ML SOLUTION FOR PERFUSION EFG	1 vial 250 ml	728755	38	d)

Active substance: J05AD01 - Foscarnet

Therapeutic indication:

Foscarnet is indicated for the induction and maintenance treatment of cytomegalovirus (CMV) retinitis in AIDS patients.

Foscarnet is also indicated for the treatment of mucocutaneous herpes simplex virus (HSV) infections in immunosuppressed patients who do not respond to treatment with acyclovir. The safety and efficacy of foscarnet in the treatment of other HSV infections (e.g., retinitis, encephalitis), neonatal or congenital disease, or HSV infection in immunocompetent individuals has not been established.

The diagnosis of non-response to acyclovir can be established clinically by establishing non-response to treatment with intravenous acyclovir (5-10 mg/kg, three times daily) for 10 days without response or by in vitro assays.

Prescription and dispensation conditions: Medical prescription. Hospital Use.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.

○ ALUTARD SQ APIS MELLIFERA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
ALK ABELLO SA	ALUTARD SQ APIS MELLIFERA INITIATION KIT (100 SQU/ML, 1.000 SQ-U/ML, 10.000 SQ-U/ML AND 100.000 SQ-U/ML)	Solution for injection 4 vials 5ml (1+1+1+1)	720665	583	a) y c)
ALK ABELLO SA	ALUTARD SQ APIS MELLIFERA 100.000 SQ-U/ML SUSPENSION FOR INJECTION, 1 vial 5 ml	Solution for injection 1 vial 5 ml	720666	525	a) y c)

Active substance: V01AA07- Insects

Therapeutic indication:

Allergen immunotherapy for patients with a documented clinical history of generalised and/or systemic IgE-mediated allergic reactions due to sensitisation to bee venom (*Apis mellifera*), confirmed by skin prick test and/or intradermal test and/or specific IgE test.

Prescription and dispensation conditions: Medical prescription. Hospital Use.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- Annual **review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ ALUTARD SQ VESPULA SPP

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
ALK ABELLO SA	ALUTARD SQ VESPULA SPP INITIATION KIT (100 SQ-U/ML, 1.000 SQU/ML, 10.000 SQ-U/ML AND 100.000 SQ-U/ML)	Solution for injection 4 vials de 5 ml (1+1+1+1)	720667	583	a) y c)
ALK ABELLO SA	ALUTARD SQ VESPULA SPP 100.000 SQ-U/ML SUSPENSION FOR INJECTION	Solution for injection 1 vial 5 ml	720668	525	a) y c)

Active substance: V01AA07- Insects

Therapeutic indication:

Allergen immunotherapy for patients with a documented clinical history of generalised and/or systemic IgE-mediated allergic reactions due to sensitisation to bee venom (*Vespula* spp.), confirmed by skin prick test and/or intradermal test and/or specific IgE test.

Prescription and dispensation conditions: Medical prescription. Hospital Use.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.

- Annual **review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

B. NEW INDICATIONS

○ XTANDI

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
ASTELLAS PHARMA SA	XTANDI 40 MG	112 soft capsules	698718	3.173,33	a) y c)
ASTELLAS PHARMA SA	XTANDI 40 MG	112 film-coated tablets	719453	3.173,33	a) y c)

Active substance: L002BB04- Enzalutamide

Therapeutic indication:

Xtandi is indicated for:

• the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC).

• the treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.

• the treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

Financed therapeutic indication:

• the treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.

• the treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

Indication considered in the application: the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC).

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Modify the price** of the cited medicine, which is listed in the table above.
- **Financing** the medicine for the treatment of high-risk non-metastatic castration resistant prostate cancer according to the following **clinical criteria** that patients must meet for its use:
  - ✓ High risk of metastasis (PSA Doubling Time (PSADT) < 6 months.
  - ✓ PSA levels ≥ 2ng/ml, with castrate testosterone levels < 50ng/dl or 1,7 nmol/l during the treatment with LHRH agonists or bilateral orchiectomy).
  - ✓ No evidence PET/CT with choline No previous or present evidence of metastatic disease, recommended diagnosis by choline PET-CT, and especially by PSMA PET/CT.
  - ✓ Good performance status (ECOG 0-1).
  - ✓ Geriatric assessment of potentially frail patients.
  - ✓ Patient comorbidities analysis.
  - ✓ Consideration of concomitant medication.
- Establishment for this medicine of **special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, without the need for a visa, to patients not hospitalised in the Pharmacy Services of Hospitals.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ LYNPARZA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
ASTRAZENECA FARMACEUTIC A SPAIN SA	LYNPARZA 100 mg	56 (7 x 8) film-coated tablets	721826	2.490	a) y c)
ASTRAZENECA FARMACEUTIC A SPAIN SA	LYNPARZA 150 mg	56 (7 x 8) film-coated tablets	721827	2.490	a) y c)

Active substance: L01XX46- Olaparib

Therapeutic indication:

Ovarian cancer

Lynparza is indicated as monotherapy for the:

- maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.
- maintenance treatment of adult patients with platinum sensitive relapsed high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Lynparza in combination with bevacizumab is indicated for the:

- maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability (see section 5.1).

Breast cancer

Lynparza is indicated as monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments.

Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy or be considered unsuitable for endocrine therapy.

Adenocarcinoma of the pancreas

Lynparza is indicated as monotherapy for the maintenance treatment of adult patients with germline BRCA1/2-mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen.

Prostate cancer

Lynparza is indicated as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent.

Financed therapeutic indication:

Lynparza is indicated as monotherapy for the maintenance treatment of adult patients with platinum sensitive relapsed high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Financing restricted to patients who meet the following criteria:

- Relapse of an ovarian, fallopian tube or primary peritoneal cancer that occurred more than 6 months after completion of the penultimate platinum treatment.
- Response to platinum treatment for the last relapse.
- At least two platinum treatments.

- BRCA 1 and/or BRCA 2 mutation (germline or somatic). Not financed in patients without mutation.

Indication considered in the application:

Lynparza is indicated as monotherapy for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

Regarding this medicinal product, the Committee **agrees** to its financing under the following conditions:

- **Modify the price** of the cited medicine, which is listed in the table above.
- **Financing** the medicine as monotherapy for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy which:
  - ✓ Have been treated with at least 6 cycles of platinum-based QT and have not been treated with bevacizumab previously.
  - ✓ Treatment should be limited to a maximum of 24 months.
- Establishment for this medicine of **special dispensation conditions** within the scope of the National Health System, consistent with limiting its dispensation, without the need for a visa, to patients not hospitalised in the Pharmacy Services of Hospitals.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

C. MODIFICATIONS TO THE PHARMACEUTICAL OFFERING

○ LUMINAL

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	NEW PRICE (€)	CRITERIA FOR REVISION
KERN PHARMA, S.L.	LUMINAL	10 vials 1 ml solution for injection	654805	5,55	6,79	Article 96.2

Active substance: N03AA02 - Phenobarbital

Therapeutic indication:

Treatment of epilepsy; status epilepticus; adjuvant treatment of acute convulsive episodes associated with tetanus; adjuvant treatment of anaesthesia.

Luminal® 20% solution for injection is particularly indicated in cases where oral medication is impossible or inadequate.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees**:

- **Modify the price** of the medicines mentioned in the terms that appear in the table above due to the change in economic, technical and health circumstances since the current price was set, the therapeutic value of the medicine and the existence of alternatives at a higher cost.

○ SAFLUTAN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	NEW PRICE (€)	CRITERIA FOR REVISION
SANTEN PHARMACEUTICAL SPAIN S L	SAFLUTAN 15 micrograms/ml	30 eye drops, solution, in single-dose container	661476	18,57	18,06	Article 96.2
ELAM PHARMA LABS S L	SAFLUTAN 15 micrograms/ml	30 eye drops, solution, in single-dose container 0,3 ml	711983	18,57	18,06	Article 96.2

Active substance: S01EE05 - Tafluprost

Therapeutic indication:

Reduction of elevated intraocular pressure in patients with open-angle glaucoma and ocular hypertension.

As monotherapy in patients:

- who may benefit from the use of preservative-free eye drops.
- who respond insufficiently to first-line treatment.
- who are intolerant or have contraindications to first-line treatment.

As adjuvant treatment to beta-blockers.

SAFLUTAN is indicated in adults ≥ 18 years.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees**:

- **Modify the price** of the medicines mentioned in the terms that appear in the table above due to the change in economic, technical and health circumstances since the current price was set and the existence of similar alternatives at a lower cost.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.

○ TAPTIQOM

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	NEW PRICE (€)	CRITERIA FOR REVISION
SANTEN PHARMACEUTICAL SPAIN S L	TAPTIQOM 15 MICROGRAMOS /ML+ 5 MG/ML	30 eye drops, solution, in single-dose container 0,3 ml	707062	18,57	16,71	Article 96.2

Active substance: association Tafluprost-Timolol. ATC S01ED51 - Timolol, combinations

Therapeutic indication:

Reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who have insufficient response to topical beta-blocker or prostaglandin analogue monotherapy, who require combination therapy and who would benefit from a preservative-free eye drop.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees**:

- **Modify the price** of the medicines mentioned in the terms that appear in the table above due to the change in economic, technical and health circumstances since the current price was set and the particularly due to the existence of similar alternatives at a lower cost or treatment cost.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.

D. ALLEGATIONS

○ DEXDOR

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
ORION PHARMA, S.L.	DEXDOR 100 micrograms/ml	Concentrate for solution for infusion 25 x 2 ml ampoules	685418	450	c)

Active substance: N05CM18 - Dexmedetomidine

Therapeutic indication:

For sedation of adult ICU (Intensive Care Unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to -3).

For sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e., procedural/awake sedation.

Financed therapeutic indication:

For sedation of adult ICU (Intensive Care Unit), limiting its prescription to those critical patients who may benefit most from the treatment, as recommended in the Protocol for the use of dexmedetomidine for the critical patient of the Sedation and Analgesia Group of the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC). These are specifically the following:

- Patient previously sedated with GABAergics who develops withdrawal syndrome as the sedative is eliminated to initiate the disconnection of mechanical ventilation.
- Patient with difficult sedation with the usual sedatives, due to tolerance, toxicity or early therapeutic failure that prevents maintaining a patient at RASS sedation level 0 to -3.
- Patient in whom spontaneous ventilation tests repeatedly fail when reducing the usual sedatives, due to adrenergic discharge and agitation or panic, preventing the withdrawal of mechanical ventilation.
- Patient in RASS 0 to -3 sedation in the process of weaning from mechanical ventilation, in which the other sedatives affect the respiratory centre and prevent progress in weaning.
- Patient on mechanical ventilation who develops delirium.

Indication considered in the application:

For sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e., procedural/awake sedation.

Prescription and dispensation conditions: Medical prescription. Hospital use.

Regarding this medicinal product, the Committee **agrees** the acceptance of the allegations to its financing under the following conditions:

- **Modify the price** of the cited medicine, which is listed in the table above.
- **Financing** the medicine restricted for non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e., procedural/awake sedation, limited to the following procedures:
    - Planned difficult airway, where the patient is to be intubated awake.
    - In functional neurosurgery (deep brain stimulation in Parkinson's surgery) and craniotomy in the awake patient
    - In haemodynamic procedures: TAVI (transcatheter aortic valve implantation)
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.

- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ RIZMOIC

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
SHIONOGI SL	RIZMOIC 200 MICROGRAMOS	28 tablets	726062	51,3	a) y c)

Active substance: A06AH05- Naldemedine

Therapeutic indication:

Rizmoic is indicated for the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative.

Prescription and dispensation conditions: Medical prescription.

Regarding this medicinal product, the Committee **agrees** the acceptance of the allegations to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- Establishment for this medicine of **special dispensation conditions**, restricting their dispensing with an inspection visa to:
    - ✓ Treatment of opioid-induced constipation (OIC) in adult oncologic patients who fail to show an adequate response with a laxative.
- Annual **review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ EYLEA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR FINANCING
BAYER HISPANIA SL	EYLEA 40MG/ML Solution for injection	1 pre-filled syringe c	695740	742	a) y c)

Active substance: S01LA05 - Aflibercept

Therapeutic indication:

Eylea is indicated for adults for the treatment of:

- neovascular (wet) age-related macular degeneration (AMD)
- visual impairment due to macular oedema secondary to central retinal vein occlusion (branch RVO or central RVO)
- visual impairment due to diabetic macular oedema (DME)
- visual impairment due to myopic choroidal neovascularisation (myopic CNV)

Prescription and dispensation conditions: Hospital use.

Regarding this medicinal product, the Committee **agrees** the acceptance of the allegations to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- **Annual review** of sales and the prices now set, to ensure that they are within the legally established parameters, and if not, proceed with their adjustment through the corresponding reduction.
- The monitoring and control of the expense caused will be carried out through the **SEGUIMED computer process** and / or any other available. The laboratory will be obliged to register in the aforementioned application and to communicate on a monthly basis the appropriate information regarding the sales of the drug to the NHS.

○ SINTROM

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	NEW PRICE (€)	CRITERIA FOR REVISION
NORGINE DE ESPAÑA, S.L.U	SINTROM 4 mg	20 tablets	654179	1,98€	2,21€	Article 96.2

Active substance: B01AA07 - Acenocumarol

Therapeutic indication:

Treatment and prophylaxis of thromboembolic conditions.

Prescription and dispensation conditions: Medical prescription. Long-term treatment.

Regarding this medicinal product, the Committee **agrees** the acceptance of the allegations to its financing under the following conditions:

- **Modify the price** of the cited medicine in the terms that appear in the table above due to the change in economic, technical and health circumstances since the current price was set and the therapeutic value of the medicine.

2. P&R REJECTIONS

A. NEW MEDICINAL PRODUCTS

A.1. NEW MEDICINAL PRODUCTS

○ CABLIVI

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR FINANCING
SANOFI AVENTIS SA	CABLIVI 10 MG	1 vial with poder + syringes with solvent + dose kit	723568	d)
SANOFI AVENTIS SA	CABLIVI 10 MG	7 vials with poder + 7 syringes with solvent + 7 dose kits	725029	d)

Active substance: B01AX07 - Caplacizumab

Therapeutic indication:

Cablivi is indicated for the treatment of adults and adolescents of 12 years of age and older weighing at least 40 kg experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.

Prescription and dispensation conditions: Medical prescription. Hospital use.

With regard to this medicine, the Committee **agrees to propose to the General Directorate the non-inclusion** of the medicine in the pharmaceutical service of the NHS, considering the uncertainty in its therapeutic value and criteria related to rationalisation of public expenditure and budget impact in the National Health System.

These are some of the legally established criteria for the selective and non-indiscriminatory funding of medicines, which are necessary to continue to ensure sustainable pharmaceutical provision of the NHS, given the continued growth in pharmaceutical provision needs.

○ NAMUSCLA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR FINANCING
EXELTIS HEALTHCARE SL	NAMUSCLA 167 MG	100 hard capsules	72500	d) y e)

Active substance: ATC: C01BB02. mexiletine

Therapeutic indication:

Namuscla is indicated for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders.

Prescription and dispensation conditions: Medical prescription.

With regard to this medicine, the Committee **agrees to propose to the General Directorate the non-inclusion** of the medicine in the pharmaceutical service of the NHS, considering criteria related to rationalisation of public expenditure and budget impact in the National Health System when compared with other currently available therapeutic alternatives.

These are some of the legally established criteria for the selective and non-indiscriminatory funding of medicines, which are necessary to continue to ensure sustainable pharmaceutical provision of the NHS, given the continued growth in pharmaceutical provision needs.

○ ALUNBRIG

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR FINANCING
TAKEDA FARMACEUTICA ESPAÑA SA	ALUNBRIG 30 MG	28 film-coated tablets	726758	d) y e)
TAKEDA FARMACEUTICA ESPAÑA SA	ALUNBRIG 90 MG	28 film-coated tablets	726797	d) y e)
TAKEDA FARMACEUTICA ESPAÑA SA	ALUNBRIG 180 MG	28 film-coated tablets	726798	d) y e)
TAKEDA FARMACEUTICA ESPAÑA SA	ALUNBRIG 90MG + 180MG	Treatment initiation pack 28 film-coated tablets (7 x 90 mg + 21 x 180 mg)	726799	d) y e)

Active substance: L01XE43 – Brigatinib

Therapeutic indication:

Alunbrig is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

With regard to this medicine, the Committee **agrees to propose to the General Directorate the non-inclusion** of the medicine in the pharmaceutical service of the NHS, considering the uncertainty in its therapeutic value and the existence of other alternatives at lower cost. It considers the criteria related to rationalisation of public expenditure for pharmaceutical provision and budget impact in the National Health System.

These are some of the legally established criteria for the selective and non-indiscriminatory funding of medicines, which are necessary to continue to ensure sustainable pharmaceutical provision of the NHS, given the continued growth in pharmaceutical provision needs.

○ LORVIQUA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR FINANCING
PFIZER. SL	LORVIQUA 25 MG	120 film-coated tablets	725703	d)

Active substance: L01XE44 – Lorlatinib

Therapeutic indication:

Lorviqua as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after:

- alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or
- crizotinib and at least one other ALK TKI.

Prescription and dispensation conditions: Medical prescription. Hospital diagnosis.

With regard to this medicine, the Committee **agrees to propose to the General Directorate the non-inclusion** of the medicine in the pharmaceutical service of the NHS, considering the existence of forms available for the same medicine.

A.2 OTHER MEDICINAL PRODUCTS

○ SAFENTI

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR FINANCING
SANIPROJECT SL	SAFENTIL 5 micrograms/ml EFG	5 ampoules 10 ml solution for intravenous perfusion	725288	d) y e)
SANIPROJECT SL	SAFENTIL 50 micrograms/ml EFG	5 ampoules 5 ml solution for intravenous perfusion	725287	d) y e)

Active substance: N01AH03- Sufentanil

Therapeutic indication:

Adults: Combined anaesthesia and analgesia. Epidural analgesia in the treatment of postoperative pain. Analgesic agent complementary to bupivacaine administered epidurally for the treatment of pain during labour and delivery.

Prescription and dispensation conditions: Medical prescription. Narcotic drug prescription. Hospital use.

With regard to this medicine, the Committee **agrees to propose to the General Directorate the non-inclusion** of the medicine in the pharmaceutical service of the NHS, considering the existence of medicines or other therapeutic alternatives for the same conditions at lower cost or lower treatment cost, and the rationalisation of public expenditure for pharmaceutical provision and budget impact in the National Health System.

These are some of the legally established criteria for the selective and non-indiscriminatory funding of medicines, which are necessary to continue to ensure sustainable pharmaceutical provision of the NHS, given the continued growth in pharmaceutical provision needs.

D. ALLEGATIONS

○ ESPIDIFEN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR FINANCING
ZAMBON. SA	ESPIDIFEN 400 mg	20 granulated sachets for oral solution mint flavour	724430	1,6

Active substance: Ibuprofen 400 mg (provided by 770 mg ibuprofen arginine).

Therapeutic indication:

Fever symptomatic treatment.

Treatment of mild to moderate pain including migraine.

Symptomatic treatment of: arthritis (including juvenile rheumatoid arthritis), osteoarthritis, ankylosing spondylitis and non-rheumatic inflammation. Relief of symptoms in primary dysmenorrhoea.

Prescription and dispensation conditions: Medical prescription.

With regard to this medicine, the Committee agrees the non-acceptance of the allegations and therefore, **proposes** to the General Directorate not to accept the exclusion of the requested financing, considering the use of the product and its alternatives.