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

SESSION 200 OF JUNE 17TH, 2020

September 22th 2020

INFORMATIVE NOTE OF THE MEETING FROM THE SPANISH INTERMINISTERIAL MEDICINAL PRODUCTS PRINCING COMMITTEE

SESSION 200 OF JUNE 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 June 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 process of allegations is disposed to the Resolution Project by the company, according to the administrative procedure.

The agreements taken in this Committee of June 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 Nomenclátor.

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 the 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, reimbursement resolution will be issued.

In the 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, an express 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 24, approving 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*) which medicinal products are financed:

Article 92

a) *Gravity, 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 spending 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 aforementioned Law.

1. P&R APPROVALS

A. NEW MEDICINAL PRODUCTS

A.1. NEW MEDICINAL PRODUCTS

○ AJOVY®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
TEVA PHARMA SL.	**AJOVY 225 MG**	1 pre-filled syringe of 1.5 ml solution for injection	725335	498	c) and d)
TEVA PHARMA SL.	**AJOVY 225 MG**	3 pre-filled syringe of 1.5 ml solution for injection	725777	1494	c) and d)

Active substance: N02CD -fremanezumab

Therapeutic indication: AJOVY is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.

Prescription and dispensation conditions: medical prescription. Hospital Diagnosis.

The Committee **agrees** to its financing under the following conditions:

- **Set the price** of the cited medicine, which is listed in the table above.
- **Restriction of the indication** to patients who meet the following criteria: Patients with 8 or more days of migraine/month (high frequency episodic migraine and in patients with chronic migraine) and THREE or more failures of previous treatments used at adequate doses for at least 3 months, one of these treatments being botulinum toxin in the case of chronic migraine.
- 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 revision 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 follow-up and control of the expense caused will be carried out by means of the **SEGUIMED computer process** and/or any other available one. The laboratory will be obliged to register in this application and to communicate on a monthly basis the timely information regarding the sales made of the drug to the NHS.

A.2. OTHER MEDICINAL PRODUCTS

○ MICAFUNGIN TEVA

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
TEVA PHARMA S.L.	**MICAFUNGIN TEVA 50MG**	1 Vial Powder for solution for perfusion	727517	102,86	d)
TEVA PHARMA S.L.	**MICAFUNGIN TEVA 100MG**	1 Vial Powder for solution for perfusion	727518	192.86	d)

Active substance: – J02AX05- Sodium Micafungin

Therapeutic indication:
Adults, teenagers ≥ 16 years and older patients:

- Treatment of invasive candidiasis
- Treatment of esophageal candidiasis in patients where intravenous therapy is appropriate
- Prophylaxis of Candida infection in patients undergoing allogeneic hematopoietic precursor cell transplantation or in patients who are expected to have neutropenia (neutrophil absolute count < 500 cells/microliter(µl)) for 10 or more days.

Children (including neonates) and adolescents < 16 years:

- Treatment of invasive candidiasis
- Prophylaxis of Candida infection in patients undergoing allogeneic hematopoietic precursor cell transplantation or in patients expected to have neutropenia (absolute neutrophil count < 500 cells/microliter(µl)) for 10 or more days

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.

○ PITAVASTATIN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
LABORATORIOS ALTER, S.A	**PITAVASTATIN ALTER 1 MG EFG**	28 film-coated tablets	728042	6.66	d)
LABORATORIOS ALTER, S.A	**PITAVASTATIN ALTER 2 MG EFG**	28 film-coated tablets	728043	9.14	d)
LABORATORIOS ALTER, S.A	**PITAVASTATIN ALTER 4 MG EFG**	28 film-coated tablets	728044	13.71	d)
LABORATORIOS ALTER, S.A	**PITAVASTATIN FARMALTER 1 MG EFG**	28 film-coated tablets	728111	6.66	d)
LABORATORIOS ALTER, S.A	**PITAVASTATIN FARMALTER 2 MG EFG**	28 film-coated tablets	728112	9.14	d)
LABORATORIOS ALTER, S.A	**PITAVASTATIN FARMALTER 4 MG EFG**	28 film-coated tablets	728114	13.71	d)
KERN PHARMA, S.L.	**PITAVASTATIN KERN PHARMA 1 MG EFG**	28 film-coated tablets	728173	6.66	d)
KERN PHARMA, S.L.	**PITAVASTATIN KERN PHARMA 2 MG EFG**	28 film-coated tablets	728174	9.14	d)
KERN PHARMA, S.L.	**PITAVASTATIN KERN PHARMA 4 MG EFG**	28 film-coated tablets	728175	13.71	d)
PENSA PHARMA, S.A.U	**PITAVASTATIN PENSA 1 MG EFG**	28 film-coated tablets	728169	6.66	d)
PENSA PHARMA, S.A.U	**PITAVASTATIN PENSA 2 MG EFG**	28 film-coated tablets	728171	9.14	d)
PENSA PHARMA, S.A.U	**PITAVASTATIN PENSA 4 MG EFG**	28 film-coated tablets	728172	13.71	d)

LABORATORIOS CINFA, S.A.	**PITAVASTATIN CINFA 1 MG EFG**	28 film-coated tablets	728219	6.66	d)
LABORATORIOS CINFA, S.A.	**PITAVASTATIN CINFA 2 MG EFG**	28 film-coated tablets	728221	9.14	d)
LABORATORIOS CINFA, S.A.	**PITAVASTATIN CINFA 4 MG EFG**	28 film-coated tablets	728222	13.71	d)

Active substance: – C10AA08- Pitavastatin

Therapeutic indication: Pitavastatin is indicated for reducing high levels of total cholesterol (CT) and LDL cholesterol (C-LDL), in adults, adolescents, and children 6 years of age and older with primary hypercholesterolemia, including familial heterozygous hypercholesterolemia and mixed (combined) dyslipidemia, when response to diet and other non-pharmacological treatments is inadequate.

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.

○ TETROFOSFOMIN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
CURIUM PHARMA SPAIN S.A.	**TETROFOSFOMIN ROTOP 0,23mg EFG**	2 vials (vial 1 and vial 2) reagent kit for radiopharmaceutical preparation.	724711	291	d)
CURIUM PHARMA SPAIN S.A.	**TETROFOSFOMIN ROTOP 0,23mg EFG**	5 vials (vial 1 and vial 2) reagent kit for radiopharmaceutical preparation.	724712	291	d)

Active substance:– V09GA02 - technetium (99mTc) tetrofosfomin

Therapeutic indication: After radioactive tagging with injectable solution of sodium pertechnetate (99mTc), the technetium (99mTc) tetrofosfomin solution obtained is indicated for:

- Myocardial imaging: Technetium (99mTc) tetrofosfomin is a myocardial perfusion agent indicated as an aid in the diagnosis and localization of ischemia and/or myocardial infarction.
- In patients undergoing myocardial perfusion scintigraphy, ECG-synchronized SPECT can be used

for the evaluation of left ventricular function (left ventricular ejection fraction and wall motility).

- Breast tumor imaging: Technetium (99mTc) tetrofosfomin is indicated as an aid to initial evaluation (e.g., palpation, mammography or alternative imaging modalities and/or cytology) for the characterization of malignancy of suspected breast lesions in which all of these other recommended tests were inconclusive.

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.

○ IMMUFALK®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
DR FALK PHARMA SPAIN SL	**IMMUFALK 100 MG**	50 film-coated tablets	700223	13,32	d)
DR FALK PHARMA SPAIN SL	**IMMUFALK 75 MG**	50 film-coated tablets	700230	9,99	d)

Active substance:– L04AX01- Other immunosuppressants. Azathioprine

Therapeutic indication:

Immufalk is indicated in immunosuppressive treatments as an adjunct to other immunosuppressants that constitute the mainstay of treatment (basic immunosuppression).

Immufalk tablets are indicated, associated with other immunosuppressive agents, in the prophylaxis of rejection in patients with allogeneic kidney, liver, heart, lung or pancreas transplants.

Immufalk is used as an immunosuppressive antimetabolite in monotherapy or, more frequently, in combination with other medications (usually corticosteroids) and/or procedures that influence the immune response. The therapeutic effect may be evident only after several weeks or months of treatment and may include a steroid-saving effect, thus reducing the toxicity associated with high doses and prolonged use of corticosteroids.

Immufalk is indicated in monotherapy or in combination with corticosteroids and/or other medications and procedures in severe cases of the following diseases, in patients with steroid intolerance or being steroid dependent, the patient does not respond adequately despite receiving treatment with high doses of steroids:

- severe active rheumatoid arthritis that cannot be kept under control with less toxic drugs (disease-modifying anti-rheumatic drugs, DMARDs)
- severe or moderately severe inflammatory bowel disease (Crohn's disease) or ulcerative colitis
- systemic lupus erythematosus
- dermatomyositis and polymyositis

- chronic active autoimmune hepatitis
- polyarteritis nodosa
- autoimmune hemolytic anemia
- chronic idiopathic refractory thrombocytopenic purpura

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.

○ VALPROIC ACID

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
AUROVITAS SPAIN, S.A.	**VALPROIC ACID AUROVITAS 500 MG**	100 extended release tablets	726898	7.72	d)
AUROVITAS SPAIN, S.A.	**VALPROIC ACID AUROVITAS 300 MG**	100 extended release tablets	726906	4.66	d)

Active substance: – N03AG01- Valproic Acid

Therapeutic indication:

- Treatment of generalised, partial or other epilepsy.
- Treatment of idiopathic mixed and generalized seizures and/or symptomatic generalized epilepsy (West and Lennox-Gastaut).
- Treatment of manic episodes in bipolar disorder when lithium is contraindicated or not tolerated. Continued treatment after the manic episode should be considered in patients who have responded to valproate for acute mania.

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.

○ LAMIVUDINE/TENOFOVIR DISOPROXIL CIPLA 300 MG/245 MG

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
CIPLA EUROPE NV BRANCH IN SPAIN	**LAMIVUDINE/ TENOFOVIR DISOPROXIL CIPLA 300 MG/245 MG**	30 film-coated tablets	724705	41.92	d)

Active substance:– J05AR12- Lamivudine -tenofovir disoproxil

Therapeutic indication: Lamivudine/Tenofovir disoproxil tablets are indicated as part of antiretroviral therapy for the treatment of adults over 18 years of age infected with human immunodeficiency virus (HIV-1).

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.

○ DISIMET®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
ALTER SA LABORATORIES	**DISIMET 50 MG/1000 MG TABLETS**	56 film-coated tablets	727860	21.63	d)

Active substance: – A10BD07 - Metformin and sitagliptin

Therapeutic indication: For adult patients with type 2 diabetes mellitus

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.

○ BUPRENORPHINE / NALOXONE

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
AUROVITAS SPAIN, S.A.U.	**BUPRENORPHINE/ NALOXONE AUROVITAS 2 MG/0,5 MG EFG**	7 sublingual tablets	727759	2.69	d)
AUROVITAS SPAIN, S.A. U.	**BUPRENORPHINE/ NALOXONE AUROVITAS 8 MG/2 MG EFG**	7 sublingual tablets	727756	10.75	d)
AUROVITAS SPAIN, S.A.U.	**BUPRENORPHINE/ NALOXONE AUROVITAS 8 MG/2 MG EFG**	28 sublingual tablets	728394	38.47	d)

Active substance: – N07BC51 – Buprenorphine/Naloxone

Therapeutic indication: Substitution treatment for opioid drug dependence, within a framework of medical, social, and psychological treatment.

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.

○ ROFLUMILAST

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
ACCORD HEALTHCARE, S.L.U	**ROFLUMILAST CCORD 500 MICROGRAMS FILM COATED TABLETS EFG**	30 tablets	728214	22,23	d)

Active substance: – R03DX07 - Roflumilast

Therapeutic indication: Roflumilast Accord is indicated for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (FEV_1 post-bronchodilator less than 50% predicted) associated

with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.

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.

○ RAPAMUNE®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
PFIZER . SL	**RAPAMUNE 1 mg/ml ORAL SOLUTION**	60 ml solution	876029	205,6	190,18	c)
PFIZER . SL	**RAPAMUNE 1 mg**	100 coated tablets	948919	359,57	332,6	c)
PFIZER . SL	**RAPAMUNE 2 mg**	30 coated tablets	724534	225,2	208,31	c)
PFIZER . SL	**RAPAMUNE 0,5 mg**	30 coated tablets	665876	52,5	48,56	c)

Active substance: – L04AA10. Selective immunosuppressants. Sirolimus.

Authorised therapeutic indication: Rapamune is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a renal transplant. It is recommended that Rapamune be used initially in combination with ciclosporin microemulsion and corticosteroids for 2 to 3 months. Rapamune may be continued as maintenance therapy with corticosteroids only if ciclosporin microemulsion can be progressively discontinued.

Financed therapeutic indication:

Rapamune is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a renal transplant. It is recommended that Rapamune be used initially in combination with ciclosporin microemulsion and corticosteroids for 2 to 3 months. Rapamune may be continued as maintenance therapy with corticosteroids only if ciclosporin microemulsion can be progressively discontinued.

Indications reason for the record:

Rapamune is indicated for the treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function.

Prescription and dispensation conditions: medical prescription.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table.
- **Annual revision 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 expenditure caused will be made through the **SEGUIMED computing process** and/or any other platform available. The laboratory will be obliged to register in said application and to communicate on a monthly basis the opportune information regarding the sales of the medicinal product to the NHS.

○ TOUJEO®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
SANOFI AVENTIS SA	**TOUJEO 300U/ml SoloStar**	3 pre-filled pens 1.5 ml solution for injection	706414	33,26	32,43	b) and c)

Active substance: – A10AE04**:** insulin glargine

Authorised therapeutic indication: Treatment of diabetes mellitus in adults, adolescents, and children from the age of 6 years.

Financed therapeutic indication: Treatment of diabetes mellitus in adults.

Indications reason for the record: Treatment of diabetes mellitus in adults, adolescents, and children from the age of 6 years.

Prescription and dispensation conditions: medical prescription.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table.

C. MODIFICATIONS TO THE PHARMACEUTICAL OFFERING

○ ITRACONAZOLE

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
GENFARMA LABORATORIO S.L	**ITRACONAZOLE ALTAN 10 mg/ml EFG**	1 vial of 25 ml concentrate and solvent for solution for perfusion	701397	64,20	77,04	Article 96.2

Active substance: – J02AC02 **–** Itraconazole

Therapeutic indication:

Altan Itraconazole is indicated in the following systemic fungal infections when first choice systemic antifungal therapy is not adequate or has not proven to be effective. (This may be due to the existence of an underlying pathology, resistance of the pathogen or toxicity of the drug) Treatment of aspergillosis, candidiasis and cryptococcosis (including cryptococcal meningitis): in immunosuppressed patients with cryptococcosis and in all patients with cryptococcosis of the central nervous system. National and/or local regulations on the correct use of antifungal agents should be considered.

Prescription and dispensation conditions: medical prescription. Medical Use.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table. Motivated by the change in the economic-technical-sanitary circumstances, the therapeutic value of this medicine and the non-existence of intravenous alternatives.

○ PLENUR®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
FAES FARMA, S.A.	**PLENUR Modified release tablets**	Pack of 100 tablets	700523	5,12€	7,17€	Article 96.2

Active substance:– N05AN01**–** lithium carbonate.

Therapeutic indication:

Prophylaxis and treatment of bipolar disorders Recurrent major depression.

Prescription and dispensation conditions: medical prescription.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table due to the change in the economic-technical-sanitary circumstances, the therapeutic value of this medicine and the incremental clinical benefit of this standard medicine in the treatment of bipolar disorder.

○ MYCOSTATIN

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
SUBSTIPHARM	**MYCOSTATIN 100,000 IU/ml, oral suspension**	60 ml bottle	790527	2	2,30	Article 96.2

Active substance:– A07AA02: Nystatin

Therapeutic indication: Treatment of the following fungal infections:

- Oral candidiasis
- Intestinal Candidiasis

Prescription and dispensation conditions: medical prescription.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table due to the change in the economic-technical-sanitary circumstances and the therapeutic value of this medicine.

○ ACALKA®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
FERRER INTERNACIONAL SA	**ACALKA 1080 mg**	100 tablets	700725	14,08	14,78	Article 96.2

Active substance:– G04BC91: Potassium, citrate

Therapeutic indication: Treatment of patients with renal lithiasis and hypocitraturia, chronic calcium oxalate stone formers, calcium phosphate.

- Uric acid lithiasis alone or accompanied by calcium lithiasis
- Tubular acidosis with calcium nephrolithiasis.

Prescription and dispensation conditions: medical prescription.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table due to the change in the economic-technical-sanitary circumstances and the therapeutic value of this medicine.

○ ASTONIN®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	ACTUAL PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REVIEW
ERN SA LABORATORIES	**ASTONIN 0,1 mg TABLETS**	40 tablets	654766	3,75	4,69	Article 96.2

Active substance:– H02AA02: Fludrocortisone

Therapeutic indication: For partial replacement therapy for primary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome.

Prescription and dispensation conditions: medical prescription.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table due to the change in the economic-technical-sanitary circumstances and the therapeutic value of this medicine.

FUNGOWAS SOLUTION®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
CHIES SPAIN, S.A.	**FUNGOWAS 1% DERMATOLOGICAL SOLUTION**	30ml bottle	969345	1,69	d)

Active substance:– D01AE14– Ciclopirox

Therapeutic indication: Treatment of dermatomycosis by dermatophytes Tinea pedis, Tinea corporis; Candidiasis, Pityriasis versicolor, Balanitis and as a complementary treatment of the couple with gynecological infection.

Prescription and dispensation conditions: medical prescription.

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

The Commission has been asked to accept the exclusion of these medicines from the pharmaceutical services of the SNS, given that they are not marketed and that there are alternative therapies with the same funded therapeutic indications.

D. STATEMETS

○ PIFELTRO®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
MERCK SHARP AND DOHME SPAIN	**PIFELTRO 100 mg**	30 film-coated tablets	724313	449.7	b) and c)

Active substance:– J05AG06 - doravirine

Therapeutic indication: Pifeltro is indicated, in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class.

Prescription and dispensation conditions: medical prescription. Hospital Use.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table.
- **Annual revision 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 expenditure caused will be made through the **SEGUIMED computing process** and/or any other platform available. The laboratory will be obliged to register in said application and to communicate on a monthly basis the opportune information regarding the sales of the medicinal product to the NHS.

○ VIZIMPRO®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
PFIZER, S.L	**VIZIMPRO 15 MG**	30 film-coated tablets	725348	2700	c)
PFIZER, S.L	**VIZIMPRO 30 MG**	30 film-coated tablets	725347	2700	c)
PFIZER, S.L	**VIZIMPRO 45 MG**	30 film-coated tablets	725349	2700	c)

Active substance:– L01XE47 - dacomitinib

Therapeutic indication: Vizimpro, as monotherapy, is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutations.

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 medicinal product in the terms that appears related in the previous table.
- Establishment for this medicine of **special reserves** in the scope of the National Health System, consisting of limiting its dispensation, without need of visa, to the patients not hospitalized in the Services of Pharmacy of the Hospitals.
- **Annual revision 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 expenditure caused will be made through the **SEGUIMED computing process** and/or any other platform available. The laboratory will be obliged to register in said application and to communicate on a monthly basis the opportune information regarding the sales of the medicinal product to the NHS.

○ ADISOCOL®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	PRICE (€)	NEW PRICE (€)	CRITERIA FOR THE REIMBURSEMENT
VISO FARMACEUTICA SL	ADISOCOL 300 mg EFG	60 tablets	723750	5,78	9,16	Article 96.2
VISO FARMACEUTICA SL	ADISOCOL 450 m, EFG	60 tablets	723749	7,51	13,74	Article 96.2

Active substance:– A05AA02- Ursodesoxycholic acid

Therapeutic indication: Dissolution of cholesterol stones in patients:

- with one or more radiolucent (negative x-ray) x-ray gallstones, preferably with a diameter of no more than 2 cm, in a well-functioning gallbladder
- rejection of a surgical procedure or where surgical intervention is not indicated;
- in which an oversaturation of cholesterol has been demonstrated by chemical analysis of the bile produced by the drainage of the duodenum.

  Primary biliary cholangitis.

  Pediatric population: Hepatobiliary disorder associated with cystic fibrosis in children from 6 to 18 years old

Prescription and dispensation conditions: medical prescription.

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

- **Modify the price** of the cited medicinal product in the terms that appears related in the previous table due to the economic-technical-sanitary circumstances and the declared commitment of supply and provisioning in the NHS.

2.P&R REJECTIONS

A. NEW MEDICINAL PRODUCTS

A.1. NEW MEDICINAL PRODUCTS

The **non-inclusion** in the pharmaceutical provision of the NHS of the medicinal products is agreed:

- **RXULTI®**

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
OTSUKA PHARMACEUTICAL S:A.	**RXULTI 1mg**	Pack of 10 tablets	724707	d) y e)
OTSUKA PHARMACEUTICAL S:A.	**RXULTI 2 mg**	Pack of 28 tablets	724739	d) y e)
OTSUKA PHARMACEUTICAL S:A.	**RXULTI 3 mg**	Pack of 28 tablets	724741	d) y e)
OTSUKA PHARMACEUTICAL S:A.	**RXULTI 4 mg**	Pack of 28 tablets	724742	d) y e)

Active substance: N05AX16- brexpiprazol

Therapeutic indication: Treatment of Schizophrenia in Adult Patients

Prescription and dispensation conditions: medical prescription.

Regarding to this medicinal product, the Committee **agrees not to include** the medicine in the pharmaceutical benefit of the NHS, considering the existence of medicines or other therapeutic alternatives for the same conditions, for which it does not provide an incremental clinical benefit, at a lower price or lower treatment cost.

○ RELAFALK ®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
DR.FALK PHARMA GMBH.	RELAFALK 200 mg	12 tablets	725657	e)

Active substance: A07AA13- Rifamycin

Therapeutic indication: In adults for the treatment of traveler's diarrhea accompanied by symptoms such as nausea, vomiting, bloating, rectal urgency, urge to defecate, and abdominal pain or intestinal cramping without clinical signs of invasive enteritis such as fever, blood, occult blood, or white blood cells in the stool.
Prescription and dispensation conditions: medical prescription.

Regarding to this medicinal product, the Committee **agrees not to include** the medicinal product in the pharmaceutical benefit of the NHS, considering there are other financed drugs from the same group of antibiotics that have additional authorized therapeutic indications, and at lower cost.

A) NEW INDICATIONS

○ PERJETA®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
ROCHE FARMA, S.A.	**PERJETA 420 mg**	1 vial of 14 ml concentrate for solution for infusion	697235	d) and e)

Active substance: L01XC13 - pertuzumab

Authorized therapeutic indications:
Early breast cancer

Perjeta is indicated for use in combination with trastuzumab and chemotherapy in:

- the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence
- the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence

Metastatic breast cancer

- Perjeta is indicated for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

Reimbursed therapeutic indications

Early breast cancer

Perjeta is indicated for use in combination with trastuzumab and chemotherapy in:

- the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence

Metastatic breast cancer

- Perjeta is indicated for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

Therapeutic indication applying for reimbursement:

- the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence

Prescription and dispensation conditions: medical prescription. Hospital Use.

Regarding to this medicinal product, the Committee **agrees not to include** the medicinal product in the pharmaceutical benefit of the NHS, considering , the existence of drugs or other therapeutic alternatives for the same conditions has been taken into account; the rationalization of public spending on pharmaceutical provision and the budget impact on the National Health System

B) STATEMETS

○ MYALEPTA®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
AEGERION PHARMACEUTICALS SPAIN SL	**MYALEPTA 3 mg**	30 vials of powder for solution for injection	723921	d)
AEGERION PHARMACEUTICALS SPAIN SL	**MYALEPTA 5,8 mg**	30 vials of powder for solution for injection	723922	d)
AEGERION PHARMACEUTICAL S SPAIN SL	**MYALEPTA 11,3 mg**	30 vials of powder for solution for injection	723437	d)

Active substance: A16AA07-Metreleptin

Therapeutic indication :

Myalepta is indicated as an adjunct to diet as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy (LD) patients:

- with confirmed congenital generalised LD (Berardinelli-Seip syndrome) or acquired generalised LD (Lawrence syndrome) in adults and children 2 years of age and above
- with confirmed familial partial LD or acquired partial LD (Barraquer-Simons syndrome), in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control.

Prescription and dispensation conditions: medical use

Regarding this medicine, the Committee **agrees not to include** the SNS in the pharmaceutical provision, considering the uncertainty regarding its clinical benefit (the results of the studies are limited since the contribution of the diet and the concomitant treatment to the benefit of the drug is unknown due to the design of the uncontrolled studies) and due to its enormous economic impact.

○ DELSTRIGO®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
MERCK SHARP AND DOHME DE ESPAÑA	**DELSTRIGO 100 MG/300 MG/245 MG**	30 film-coated tablets	724315	e)

Active substance: J05AR24 – Lamivudine, disoproxyl tenofovir and doravirine

Therapeutic indication:

Delstrigo is indicated for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir.

Prescription and dispensation conditions: medical prescription

Regarding this medicine, the Committee **agrees not to include** the SNS in the pharmaceutical provision, due to the existence of other therapeutic alternatives of the same combination of this drug at a lower price or lower cost of treatment.

○ KYMRIAH®

MANUFACTURER	TRADENAME	PHARMACEUTICAL FORM	NATIONAL CODE	CRITERIA FOR THE REVISION
NOVARTIS FARMACEUTICA S.A.	**KYMRIAH 1,2 x 10e6 - 6,0 x 10e8 cells dispersion for infusion**	1-3 infusion bags (1 dose for individual treatment)	72357	Article 96.2

Active substance: tisagenlecleucel

Therapeutic indication: Kymriah is indicated in the treatment of:

- Paediatric and young adult patients up to and including 25 years of age with B-cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse
- Adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

Prescription and dispensation conditions: medical prescription. Hospital Use.

Regarding this medicinal product, the Committee does not amend the decision to finance the medicinal product under the terms requested by the company. It is considered that the various organizational measures implemented by the competent health authorities make it possible to ensure compliance with the resolution in the terms set out in its current wording.