Results 156 patients were included and classified into two groups: switchers that were treated with OI and were switched to CT-P13 (n = 85, 54%) and initiators that did not receive OI prior to CT-P13 treatment (n = 71, 46%). 23 (27%) switchers and 35 (49%) initiators discontinued CT-P13 after 12 months. Main reasons for CT-P13 discontinuation were lack of efficacy (n = 21, 36%) and secondary loss of response (n = 16, 28%). Lack of active training and coordination among healthcare professionals and little patient education may have exacerbated patients' subjective complaints and increased the CT-P13 discontinuation rate.
Conclusion and relevance Lack of efficacy and secondary loss of response were the main reasons for the high CT-P13 discontinuation rate observed in a large tertiary hospital. Coordination between the various healthcare professionals involved with the patients is a prerequisite for biosimilars to achieve their maximum cost-saving potential.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

2SPD-006 DEVELOPMENT OF A PRIORITISATION PROTOCOL FOR THE USE OF IMMUNOGLOBULINS IN VIEW OF THE GLOBAL SUPPLY PROBLEM

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Background and importance Highly purified immunoglobulins (95%) are obtained from the purification of human plasma extracted from healthy donors. The mechanism of action consists of an antigen-specific activity, exerting immunomodulatory functions in addition to those of the natural immunoglobulins. The increase in demand, the dependence exclusively on plasma donations, and the pandemic situation have reduced the supply of immunoglobulins worldwide.
Aim and objectives To elaborate a protocol at regional level (seven hospitals) to prioritise, rationalise and reduce the use of immunoglobulins in view of the worldwide supply problem.
Material and methods A multidisciplinary work team was created comprising professionals involved in the use of these therapies (immunologists, haematologists, internists, neurologists, paediatricians and pharmacists). The main pathologies involved were specified.

Subsequently, the indications depicted in the technical data sheet and the available scientific evidence were reviewed, to define three priority groups:

- Priority 1: Necessary treatment, there is no other therapeutic alternative.
- Priority 2: Pathologies or clinical situations where the use of immunoglobulins is recommended.
- Priority 3: Clinical situations without sufficient scientific evidence.

Finally, the indications and dose regimen of all patients under active treatment were reviewed.
Results The work team defined Priority 1 as follows:

- Chronic treatments: primary and secondary immunodeficiencies, CAR–T hypogammaglobulinaemia in paediatrics, pure motor chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy.
- Acute treatments: Kawasaki disease, primary immune thrombocytopenia (PIT) before undergoing urgent surgery or PIT with severe thrombopenia/large bleeding diathesis.

Priority 2 included: Guillain-Barré syndrome, myasthenia gravis, PIT with high risk of bleeding, CIDP (excluding pure motor), severe neonatal sepsis, alloimmune haemolytic disease in neonates, alloimmune neonatal thrombocytopenia, haemophagocytic syndrome and paediatric multisystem inflammatory syndrome due to SARS-CoV-2.

Pathologies not mentioned above were considered Priority 3, being evaluated by a multidisciplinary Experts Committee.

After reviewing the active treatments, 21% of them were temporarily suspended. Since the protocol approval, eight new cases have been assessed as Priority 3, with only one of them being denied.
Conclusion and relevance The creation of the protocol has made it possible to rationalise the use of immunoglobulins, reducing their consumption and promoting the use of therapeutic alternatives. Thus, completely necessary treatments are guaranteed through equitable and equal access throughout the region.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

2SPD-008 NETWORK META-ANALYSIS OF IMMUNOTHERAPIES IN UNTREATED ADVANCED OR METASTARIC OESOPHAGEAL SQUAMOUS CELL CARCINOMA

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Background and importance ESCORT-1st trial reported a benefit for overall survival (OS) of camrelizumab plus chemotherapy (Cam+CT) combination over chemotherapy (CT) in September 2021. Regimens with platinum agents have been the standard first-line treatment for advanced or metastatic oesophageal squamous cell carcinoma (mESCC) for decades.
Aim and objectives To develop a network meta-analysis (NMA) to provide an efficacy comparison of treatments for untreated patients with mESCC.
Material and methods A review in Pubmed and UpToDate databases was conducted on 3 October 2021. Inclusion criteria: randomised clinical trials (RCTs) including immune checkpoint inhibitor therapies (camrelizumab, pembrolizumab, nivolumab and ipilimumab) as first-line treatment of mESCC. Exclusion criteria: RCTs without a common comparator linking cited drugs. Efficacy endpoint was OS. NMA used

combined direct and indirect evidence to estimate pooled hazard ratios (HR) by Bayesian methods. Fixed and random effects were considered. Deviance information criteria (DIC) statistics were evaluated to compare models. I^2 determined the proportion of variability in outcomes due to heterogeneity.
Results Three RCTs were selected. The RCTs assessed the following regimens: Cam+CT, nivolumab plus ipilimumab (N+I), nivolumab plus chemotherapy (N+CT), pembrolizumab plus chemotherapy (Pem+CT) and CT. The common comparator was CT. Two RCTs included patients with 0–1 performance status (ECOG). Cam+CT study evaluated patients with a life expectancy of at least 12 weeks. Results of N+I and N+CT were obtained from a congress abstract. Similar values of DIC (difference <5, no minimun relevance) were estimated for fixed- and random-effects models. Fixed-effects model was selected due to the higher precision of data. I^2 was 25%. Regarding Cam+CT (therapy with the greatest magnitude of effect), HR for OS were: 1.0 (95% CI 0.76 to 1.4) vs Pem +CT, 1.1 (95% CI 0.78 to 1.4) vs N+CT, 1.1 (95% CI 0.81 to 1.5) vs N+I and 1.4 (95% CI 1.1 to 1.8) vs CT. No statistically significant differences were found among Cam+CT, Pem+CT, N+CT and N+I. All schemes with immune checkpoint inhibitor drugs were superior to CT.
Conclusion and relevance This updated NMA showed a greater efficacy benefit of combinations with immunotherapeutic agents over CT in untreated patients with mESCC. Standard first-line therapy could be modified. Safety and efficiency criteria should also be considered in the therapeutic positioning of drugs in this clinical context.

REFERENCES AND/OR ACKNOWLEDGEMENTS
None
Conflict of interest No conflict of interest

2SPD-013 INCREASE IN HEALTHCARE COSTS WITH FIDAXOMICIN VERSUS VANCOMYCIN FOR *CLOSTRIDIUM DIFFICILE* TREATMENT

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Background and importance *Clostridium difficile* (*CD*) colonises the human intestinal tract after the normal flora has been disrupted (in association with antibiotic therapy). Clinical guidelines use fidaxomicin as first-line treatment in patients at greater risk for recurrence (age >65 years, compromised immunity, severe CD infection) in accordance with 2021 Infectious Diseases Society of America (IDSA).
Aim and objectives Evaluation of the cost increase in the treatment of *CD* if patients are treated with fidaxomicin instead of vancomycin after the failure of first-line treatment or as first-line treatment according to the age recommendations of the IDSA.
Material and methods Retrospective observational study that included patients diagnosed with pseudomembranous colitis and treated with oral vancomycin for *CD* from 1 October 2020 to 30 September 2021. Clinical sources used were from FarmaTools and the Electronic Medical Record Selene.
Results 97 patients were analysed; 48.45% men, median age 72 (SD 16) years. 9 were empirically treated. 88 pacients were positive for *CD*. 5 patients died from another pathology during treatment (3 during the first-line and 2 during the second-line treatment).

73 patients (75.26%) (43.84% men) only needed one line of treatment with vancomycin to achieve a cure. The cost of vancomycin treatment for these patients was € 3216.

19 patients (19.59%) (63.16% men) required a second (15 patients) or third line (4 patients) of treatment after the failure of the previous lines. The cost of vancomycin treatment for these patients was € 2266. These patients could have been treated with fidaxomicin. The total cost would have been increased to € 30 300.

71 patients (73%) at the time of diagnosis were older than 65 years; 83% first line, 9.86% second line and 7.14% third line. The cost of vancomycin treatment for these patients was € 5461. Following the IDSA criteria, these patients could have been treated from the beginning with fidaxomicin. The total cost would have been increased to € 102 453.
Conclusion and relevance The use of fidaxomicin represents a very high increase in healthcare costs compared to vancomycin. In our study all the patients were cured with the use of vancomycin. It should also be noted that in clinical trials and meta-analyses, fidaxomicin achieves a modest superior efficacy compared to vancomycin.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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2SPD-014 APPROPRIATENESS OF USTEKINUMAB THERAPY PRESCRIPTION AND REAL-LIFE CONDITION USE IN CROHN'S DISEASE

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Background and importance For the patient with moderate to severe Crohn's disease, first-line options for induction therapy include a biologic agent. Tumour necrosis factor alpha antagonists (anti-TNFα) are recognised as the primary therapeutic option. Ustekinumab is an anti-IL 12/23 antibody that has been approved for use in patients who have had an inadequate response, show loss of response or are intolerant to conventional treatment or anti-TNFα or have contraindications.
Aim and objectives To describe the prescription of ustekinumab in real-life conditions in our hospital and to assess the appropriateness of ustekinumab prescription.
Material and methods All patients treated with ustekinumab were included during the period 2017–2021. Demographic variables: previous anti-TNFα agents used, dose or interval intensification, drug trough antidrug antibodies measurements, primary or secondary failure, concomitant medication, ustekinumab dose, and reason for switching (biomarkers, symptoms, mucosal inflammation) were collected. Data were obtained from the electronic medical record and prescription application. Appropriateness of prescription: therapeutic drug monitoring, intensification before switching, and contraindications to use of anti-TNFα.
Results The results are shown in Table 1.
Conclusion and relevance Given the high number of patients without therapeutic drug monitoring or with dose or interval intensification, it was decided to create an interdisciplinary commission made up of digestive and pharmaceutical experts in order to optimise drug prescribing in Crohn's disease.