

intravenous formulations and allows for a greater number of accesses to therapies given the reduced administration times.

Aim and Objectives The objective of this work is to calculate the direct costs of the medical devices necessary for infusion therapy and the indirect costs of the nursing staff responsible for setting up intravenous therapies for daratumumab.

We studied the 2022 data of three local healthcare companies.

Material and Methods With company software we determined the cost of the devices used in intravenous and subcutaneous preparation and the number of patients receiving daratumumab therapy in 2022, considering for each patient 24 cycles of therapy as indicated in the dosage schedules.

Results The cost calculated for a single intravenous preparation is € 12.01, considering the following devices necessary for administration:

Two vial-spikes € 2.84, two syringes with connectors € 2.48, clave-valve € 2.76, bag € 0.60, syringe-luerlock for diluent € 0.50, secondary infusion set € 2.20, cap-cap € 0.25, UV-protector bag € 0.25.

The cost for subcutaneous administration is different, equal to € 3.29 for vial-spike, syringe and connector, UV-protector bag and cap-cap.

The indirect cost calculated on the average hourly nursing cost of € 27.83 and considering a 10-minute set-up commitment for two nursing units is € 9.28.

In 2022, 55 patients in healthcare company 1, 69 patients in healthcare company 2, and 12 patients in healthcare company 3 were treated with daratumumab.

Conclusion and Relevance The total cost of the devices and the healthcare staff responsible for preparing the infusion is equal to € 21.66 compared to € 3.29 for the cost of preparing the subcutaneous injection. The subcutaneous administration is more convenient than intravenous, with a saving of € 18.55 per administration. Since the prices of the two formulations of daratumumab are equal, this corresponds to an actual saving.

This saving for the entire year 2022 and for the 24 planned administration cycles would produce a reduction in spending, accounted for in the set-up costs, equal to € 24,486 for healthcare company 1, € 35,885 for healthcare company 2, and € 6,241 for healthcare company 3.

To this we must add an increase in the safety of the operators who prepare and administer, greater patient compliance and a decrease in the social costs of the patient undergoing therapy.

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Conflict of Interest No conflict of interest.

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HTA ANALYSIS FOR THE INCLUSION OF ANDEXANET ALFA (AA) WITHIN THE HOSPITAL THERAPEUTIC HANDBOOK (HTH) – THE EXPERIENCE OF AN ITALIAN CENTRE SPECIALISING IN CARDIOVASCULAR DISEASES

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Background and Importance The drug Andexanet Alfa (AA), an anti-haemorrhagic antidote capable of rapidly reversing the effect of factor Xa inhibitor DOACS (Apixaban, Rivaroxaban), was recently introduced on the market. The 4-factor prothrombin complex (CPP4), already in use at our centre, also has the same indication.

Aim and Objectives In collaboration with a haematologist and a cardiologist-anaesthetist, an HTA analysis was conducted with the aim of evaluating the real need for the inclusion of AA within the Hospital Therapeutic Handbook (HTH) and its use in cardiac surgery emergency situations and cardiovascular emergency.

Material and Methods A brief review of the literature currently available on various search engines (PubMed, clinicaltrials.gov) was conducted by the hospital pharmacy, looking in particular for comparison studies between AA and CPP4. In parallel, a search was conducted for poison control centres (PCC) and hospital centres close to the facility that had the drug available, an economic evaluation and an analysis of the Summary of Product Characteristics (SmPC).

Results From the retrospective studies analysed (eight, of which only three meta-analyses), data were collected and summarised in terms of efficacy/haemostasis rate (AA: 77.88% vs CPP4: 76.47%, average data) and safety/incidence of post-treatment thromboembolic events (AA: 10.47% vs CPP4: 5.98% average figure).

From the parallel research, the following results emerged: availability of the antidote (one PCC and two hospital centres); treatment costs (AA: Euro 52,666.52 vs CPP4: Euro 3795.90); reimbursement (non-reimbursable drug); AA preparation/infusion times (approximately 2h 30).

Conclusion and Relevance The analysed studies, subject to bias due to the variability of the analysed sample, were mainly focused on intracranial haemorrhage events and not on cardiac surgical complications. From these, it also emerged that AA promotes a refractoriness to the anticoagulant effect of unfractionated heparin, making the use of AA incompatible in patient candidates for a cardiac surgical procedure that requires pre-heparinisation.

Therefore, by virtue of the poor and unfavourable quality of the trials and the unfavourable cost-effectiveness and risk-benefit ratios, it was not considered necessary to introduce the drug within the HTH.

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