HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
24 JUNE 2020

The legally binding text is the original French opinion version

tirofiban hydrochloride monohydrate
AGRASTAT 50 micrograms/ml solution for infusion
AGRASTAT 250 micrograms/ml concentrate for solution for infusion

New indication

Key points

Unfavourable opinion for reimbursement in the reduction of the risk of major cardiovascular events in patients with acute myocardial infarction (STEMI) intended for percutaneous coronary intervention (PCI).

Role in the care pathway?

In the event of coronary syndromes with ST elevation undergoing PCI, patients should be given acetylsalicylic acid (ASA) and an oral P2Y12 receptor inhibitor, prasugrel or ticagrelor or clopidogrel, as soon as possible. Injection with intravenous cangrelor may be considered in patients without prior P2Y12 inhibitor therapy in whom the oral form is not possible. An anticoagulant therapy (unfractionated heparin) should be co-administered with the antiplatelet therapy.

Role of the medicinal product in the care pathway

AGRASTAT (tirofiban) has no role in the reduction of the risk of major cardiovascular events in patients with acute myocardial infarction (STEMI) intended for percutaneous coronary intervention (PCI).

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ ST elevation acute coronary syndromes are serious, life-threatening clinical situations.

◗ AGRASTAT (tirofiban) is a preventive treatment to reduce the risk of major cardiovascular events.

◗ Considering:
- the absence of data with a good level of evidence demonstrating the efficacy of tirofiban in routine or pre-hospital use, versus placebo / no tirofiban / or an active comparator, in terms of reduction in morbidity and mortality;
- the known safety profile confirmed in these studies, and marked by bleeding and thrombocytopaenia,
- the absence of data enabling identification of a subpopulation of patients who would most benefit from the treatment,

the efficacy/adverse effects ratio of AGRASTAT (tirofiban) has not been adequately established.

◗ There are alternatives available in France in patients with ST elevation ACS undergoing PCI (see chapter on clinically relevant comparators).

◗ AGRASTAT (tirofiban) has no role in the reduction of the risk of major cardiovascular events in patients with acute myocardial infarction (STEMI) intended for percutaneous coronary intervention (PCI).

◗ Public health impact:
Considering:
- the seriousness of acute coronary syndromes,
- their high prevalence,
- the partially met medical need,
- the lack of response provided by AGRASTAT (tirofiban) to the identified medical need (in particular, due to the absence of any robust demonstration of a benefit in terms of reduction of ischaemic events, versus placebo or an active comparator),
- the lack of a demonstrated impact on the patient's care and/or life pathway, in the absence of a posteriori quality of life data,
- the absence of an impact on the organisation of care,

AGRASTAT (tirofiban) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of AGRASTAT (tirofiban) is insufficient to justify its funding by the French national health insurance system in the reduction of the risk of major cardiovascular events in patients with acute myocardial infarction (STEMI) intended for percutaneous coronary intervention (PCI).

The Committee issues an unfavourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the indication extension for the reduction of the risk of major cardiovascular events in patients with acute myocardial infarction (STEMI) intended for percutaneous coronary intervention (PCI).

Clinical Added Value

Not applicable.