SUMMARY

atogepant

AQUIPTA 10 mg and 60 mg,

tablet

First assessment

Original French opinion adopted by the Transparency Committee on 6 December 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Migraine is a chronic disabling disease which, due to the frequency and severity of attacks, can lead to severe impairment of quality of life.
- The proprietary medicinal products AQUIPTA (atogepant) are medicinal products intended to prevent acute migraine episodes.
- In view of:
  - the evidence of the superiority of atogepant only versus placebo in episodic and chronic migraine, and in particular in a study (ELEVATE study) in patients who failed to respond to 2 to 4 prophylactic treatments with a moderate short-term effect size,
  - the evidence of the superiority versus placebo in terms of quality of life (ranked secondary outcome measures) in patients who failed to respond to 2 to 4 prophylactic treatments with an effect size corresponding to a variation of 17.9 points out of 100 on the restrictive subscale of the MSQ questionnaire (version 2.1), in patients with a score of 42.3 points at inclusion, and a variation of -6.4 points out of 78 on the HIT-6 migraine impact score in patients with a score of 64.5 points at inclusion,
  - the robust short-term safety data available, and uncertainties about long-term safety, particularly in terms of cardiovascular risks in a context where patients with severe cardiovascular disease were excluded from the studies,

  the efficacy/adverse effects ratio is high in adult patients presenting with at least 8 migraine days per month, who have failed to respond to at least two prophylactic treatments and do not have any cardiovascular impairment (patients with established cardiovascular or cerebrovascular disease, with recent history (< 6 months) of acute coronary syndrome or stroke/TIA, or AHT).

  In other clinical contexts, including patients with less than 8 migraine days per month, patients who are treatment-naïve or have failed to only one prophylactic treatment, and patients with

cardiovascular impairment, the efficacy/adverse effects ratio of AQUIPTA (atogepant) cannot be established.

➔ AQUIPTA (atogepant) is a drug option for adult patients suffering from severe migraines with at least 8 migraine days per month, who have failed to respond to at least two prophylactic treatments and do not have any cardiovascular impairment (patients with established cardiovascular or cerebrovascular disease, with recent history (< 6 months) of acute coronary syndrome or stroke/TIA, or AHT).

In other clinical contexts including patients with less than 8 migraine days per month, patients who are treatment-naïve or have failed to respond to only one prophylactic treatment, and patients with severe cardiovascular impairment, AQUIPTA (atogepant) has no role in the therapeutic strategy.

➔ Public health benefit

In view of:

- the severity of the disease and its prevalence,
- the partially met medical need in severe migraine contexts (≥ 8 migraine days per month) after failure to respond to at least two prophylactic treatments with the need for more effective alternative basic medicinal treatments with less adverse effects,
- a partial response to the identified need on account of:
  - the evidence of superiority in terms of efficacy *versus* placebo only in the prophylactic treatment of episodic and chronic migraine, mainly in adult patients who have failed to respond to at least two prophylactic treatments, albeit with a moderate effect size,
  - the lack of evidence of an additional impact in terms of quality of life given the robust data *versus* placebo only in patients who have failed to respond to 2 to 4 prophylactic treatments,
  - the expected additional impact on the care and/or life pathway due to its oral administration compared to other anti-CGRP products which are administered by injection,

AQUIPTA (atogepant) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of AQUIPTA (atogepant) 10 mg and 60 mg, tablets, is:

- **substantial only for the preventive treatment of migraine in adult patients suffering from severe migraines with at least 8 migraine days per month, who have failed to respond to at least two prophylactic treatments and do not have cardiovascular impairment (patients with established cardiovascular or cerebrovascular disease, with recent history (< 6 months) of acute coronary syndrome or stroke/TIA, or AHT),**
- **insufficient to justify public funding in the other marketing authorisation situations, in view of the alternatives available.**

The Committee approves inclusion of AQUIPTA (atogepant) 10 mg and 60 mg, tablets, in the list of covered drugs for outpatients and in the list of covered drugs for inpatients for the preventive treatment of migraine for adult patients suffering from severe migraine with at least 8 days of migraine per month, who have failed to respond to at least two prophylactic treatments and do not have cardiovascular impairment (patients with established cardiovascular or cerebrovascular disease, with recent history (< 6 months) of acute coronary syndrome or stroke/TIA, or AHT), and at the marketing authorisation dosages.

The Committee disapproves the inclusion of AQUIPTA (atogepant) 10 mg and 60 mg, tablets, in the list of covered drugs for outpatients and in the list of covered drugs for inpatients for the other Marketing Authorisation situations.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

➔ **Within the selected reimbursement scope**

Considering:

- the evidence of superiority of atogepant 60 mg and 10 mg versus placebo only in episodic and chronic migraine, and in particular in a study involving patients who had failed to respond to 2 to 4 prophylactic treatments, with a moderate effect size on the variation of the number of migraine days per month between inclusion and 12 weeks for atogepant 60 mg only (primary outcome measure): -2.4 days, in patients with 9 migraine days per month on average at inclusion,
- the evidence of the superiority versus placebo in terms of quality of life (ranked secondary outcome measures) in patients who failed to respond to 2 to 4 prophylactic treatments with an effect size corresponding to a variation of 17.9 points out of 100 on the restrictive subscale of the MSQ questionnaire (version 2.1), in patients with a score of 42.3 points at inclusion, and variation of -6.4 points out of 78 on the HIT-6 migraine impact score in patients with a score of 64.5 points at inclusion,
- the robust short-term safety data available and uncertainties about long-term safety, particularly in terms of cardiovascular risks in a context where patients with severe cardiovascular diseases were excluded from the studies,
- the lack of robust data compared to an active comparator in a context where all of the patients in the ELEVATE study had failed to respond to 2 to 4 prior prophylactic oral treatments, with the majority failing to respond to 2 prophylactic treatments (56.0%),
- and despite the medical need in this population with severe migraine whose quality of life is particularly impaired,

the Committee deems that AQUIPTA (atogepant) provides no clinical added value (CAV V) for the preventive treatment of migraine for adult patients suffering from severe migraines with at least 8 migraine days per month, who have failed to respond to at least two prophylactic treatments and do not have cardiovascular impairment (patients with established cardiovascular or cerebrovascular disease, with recent history (< 6 months) of acute coronary syndrome or stroke/TIA, or AHT).

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