SUMMARY

aripiprazole

ABILIFY MAINTENA 720 mg and 960 mg

prolonged-release suspension for injection in pre-filled syringe

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 23 October 2024

Summary of opinion

Favourable opinion for reimbursement in the maintenance treatment of schizophrenia in adult patients stabilized with aripiprazole.

No clinical added value of the new forms, ABILIFY MAINTENA 720 mg and ABILIFY MAINTENA 960 mg (prolonged-release aripiprazole) prolonged-release suspension for injection in pre-filled syringe **as a two-monthly injection**, compared to the forms, ABILIFY MAINTENA 300 mg and ABILIFY MAINTENA 400 mg (prolonged-release aripiprazole **as a monthly injection**), already available.

Transparency Committee's conclusions

Clinical Benefit

- Schizophrenia is a severe disease in terms of the disability it causes, the age of onset (late adolescence, young adulthood) and its personal, social, family or professional impact. It usually has a chronic course, due to residual symptoms or relapses, which are common in the disease. It is often associated with numerous psychiatric and somatic comorbidities.
- The proprietary medicinal products ABILIFY MAINTENA 720 mg and ABILIFY MAINTENA 960 mg (prolonged-release aripiprazole) prolonged-release suspension for injection in pre-filled

Haute Autorité de Santé – Communication and Information Department

5 avenue du Stade de France – 93218 SAINT-DENIS LA PLAINE CEDEX – France. Tel.: +33 (0)1 55 93 70 00

syringe **as a two-monthly injection** are a maintenance treatment of schizophrenia in adult patients stabilized with aripiprazole.

- The efficacy/adverse effects ratio of the proprietary medicinal products ABILIFY MAINTENA 720 mg and ABILIFY MAINTENA 960 mg (prolonged-release aripiprazole) prolonged-release suspension for injection in pre-filled syringe **as a two-monthly injection** is high in the maintenance treatment of schizophrenia in adult patients stabilized with aripiprazole.
- The proprietary medicinal products ABILIFY MAINTENA 720 mg and ABILIFY MAINTENA 960 mg (prolonged-release aripiprazole) prolonged-release suspension for injection in pre-filled syringe **as a two-monthly injection** are therapeutic alternatives in the maintenance treatment of schizophrenia in adult patients stabilized with aripiprazole, in situations where increasing the interval between injections is not detrimental to the patient's medical follow-up, in view of the available therapies.

Public health benefit

The proprietary medicinal products ABILIFY MAINTENA 720 mg and ABILIFY MAINTENA 960 mg (prolonged-release aripiprazole) prolonged-release suspension for injection in pre-filled syringe **as a two-monthly injection** are unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of the proprietary medicinal products ABILIFY MAINTENA 720 mg and ABILIFY MAINTENA 960 mg (prolonged-release aripiprazole) prolonged-release suspension for injection in pre-filled syringe as a two-monthly injection is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Recommended reimbursement rate: 65%Clinical Added Value

Considering:

- **pharmacokinetic data having reported similar mean plasma aripiprazole concentrations and areas under the time-concentration curve between prolonged-release aripiprazole 960 mg as a two-monthly injection after the 4th dose and prolonged-release aripiprazole 400 mg as a monthly injection after the 7th or 8th doses in a comparative study for which several limitations were identified (off-label clinical indication (bipolar disorder type I) in 30% of cases, prior aripiprazole treatment for only a third of patients, data only available for the 960 mg strength, high attrition rates, transposability),**
- **the absence of efficacy data versus an active comparator enabling to position the medicinal product in the care pathway, in a context in which the other prolonged-release therapeutic alternatives that can be administered in adults stabilized with aripiprazole (i.e., prolonged-release aripiprazole monthly injection or prolonged-release risperidone two-monthly injection) have demonstrated their non-inferiority versus an active comparator,**
- **the absence of data supporting an improvement in patient compliance, safety and/or quality of life compared to monthly injections, in particular,**

but taking into account

- **the known efficacy profile of aripiprazole as monthly injections currently available,**
- **the safety data having reported a similar safety profile between two-monthly injections and monthly injections, although with more injection site reactions (18.2% versus 9.0%, respectively) and weight gain (22.7% versus 20.9%, respectively),**
- **the benefit of having dosage forms enabling a different administration schedule, without, however, a formally demonstrated improvement in terms of quality of life or acceptability,**

the Committee deems that the proprietary medicinal products ABILIFY MAINTENA 720 mg and ABILIFY MAINTENA 960 mg (prolonged-release aripiprazole) prolonged-release suspension for injection in pre-filled syringe as a two-monthly injection are range supplements that do not provide any clinical added value (CAV V) compared to the ABILIFY MAINTENA 300 mg and ABILIFY MAINTENA 400 mg (prolonged-release aripiprazole as a monthly injection) forms already listed.