Repatha on the list of exceptional medication in Québec

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http://www.ramq.gouv.qc.ca/SiteCollectionDocuments/liste_med/liste_med_2018_02_01_en.pdf

EVOLOCUMAB:

- for treatment of persons suffering from homozygous familial hypercholesterolemia (HoFH) confirmed by genotyping or by phenotyping:

  - where two hypolipemiants of different classes at optimal doses are not tolerated, are contraindicated or are ineffective;

  Phenotyping is defined by the following three factors:
  - a concentration in the low-density lipoprotein cholesterol (LDL-C)) > 13 mmol/l before the beginning of a treatment;
  - the presence of xanthomas before age 10;
  - the confirmed presence in both parents of heterozygous familial hypercholesterolemia.

  The initial request is granted for a maximum period of four months.

  Upon subsequent requests, the physician must provide information making it possible to establish the beneficial effects of the treatment, that is, a decrease of at least 20% in the LDL-C compared to the basic levels. Subsequent requests are authorized for a maximum duration of 12 months.

  Authorizations for evolocumab are given for a maximum dose of 420 mg every two weeks.

- for treatment of adults suffering from heterozygous familial hypercholesterolemia (HeFH) confirmed by genotyping or by phenotyping, for whom use of a statin at the optimal dose in association with ezetimibe has not allowed for adequate control of the cholesterolemia, unless there is a serious intolerance or a contraindication.

  In patients without atherosclerotic cardiovascular disease, adequate control of the cholesterolemia is defined as a reduction in the LDL-C concentration of at least 50% compared to the basic level, that is, before any lipid lowering drug treatment.

  In patients with atherosclerotic cardiovascular disease, adequate control of the cholesterolemia is defined as the attainment of a LDL-C concentration of < 2 mmol/l.

  Phenotyping is defined as a LDL-C concentration > 4 mmol/l in children under age 16 or > 4.9 mmol/l in adults before the beginning of a treatment and at least one of the following:
  - a history of HeFH confirmed by genotyping in a first-degree relative;
  - the presence of a mutation, causing a familial hypercholesterolemia, of the LDLR, ApoB or PCSK9 genes in a first-degree relative;
  - the presence of xanthomas in the person or in one of the first-degree or second-degree relatives;
  - the presence of a corneal arcus before age 45 in a first-degree relative;
  - a family history of LDL-C concentration > 4.9 mmol/l in an adult first-degree relative or ≥ 4 mmol/l in a first-degree relative under age 18;
  - a family history of total cholesterol concentration > 7.5 mmol/l in an adult first-degree or second-degree relative or > 6.7 mmol/l in a first-degree relative under age16.

  The initial request is authorized for a maximum period of four months.

  Upon subsequent requests, the physician must provide information making it possible to establish the beneficial clinical effects of the treatment, that is, a decrease ≥ 40 % in the LDL-C concentration compared to the value before the beginning of treatment with evolocumab. Subsequent requests are authorized for a maximum duration of 12 months.

  Authorizations for evolocumab are given for a maximum dose of 140 mg every two weeks or 420 mg every month.