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National Health Care Institute
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Contact
Ms. N. Stam

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Our reference
2024004157

Date 23 May 2024
Re: Progress report conditional admission procedure for orphan drugs, conditionals and exceptionals

Dear Ms Dijkstra,

Please find enclosed the Progress Report for the conditional inclusion procedure for orphan drugs, conditionals and exceptionals for the reporting year 2023.

With the conditional inclusion procedure (CI) for orphan drugs, conditionals and exceptionals, the National Health Care Institute is committed to proactive package management to promote appropriate care. The CI process has been in force since October 2019. With this procedure, patients with a severe disorder and an unmet treatment need could, under conditions, be eligible for reimbursement of promising medicines that, due to insufficient evidence, do not yet meet the established medical science and medical practice. After sufficient evidence has been gathered for the test on the established medical science and medical practice, the medicinal product is either definitively included in or excluded from the basic health care package.

Once a year, the research group and/or registration holder organises a meeting to discuss the progress and relevant interim findings of the CI process with all stakeholders. Based on this annual monitoring point, the National Health Care Institute assesses progress based on, inter alia, patient inclusion and feasibility of the research process. The National Health Care Institute will create a report on this subject, in which it will also advise on any adjustment or termination of the CI processes.

Since October and November 2021, the first three CI processes were initiated for four medicinal products. One of the three procedures with two medicinal products (larotrectinib (Vitrakvi®) and entrectinib (Rozlytrek®)) was successfully completed in 2023. Both medicinal products have been reimbursed from the basic health care package since 1 September 2023. The National Health Care Institute has advised that the other two CI procedures, for rhPTH 1-84 (Natpar®) and ataluren (Translarna®) should be terminated early. We already informed your predecessor about this on 21 February 2024 (our reference number: 2024004174).

Since the National Health Care Institute is currently meeting with stakeholders

about several medicinal products, it expects to present various potential candidates in the coming year. Teduglutide (Revestive®), atidarsagene autotemcel (Libmeldy®) and risdiplam (Evrysdi®) were already identified as potential CI candidates in 2023. The National Health Care Institute expects to launch new CI procedures for these products in 2024, provided that the covenant phase is successfully completed and a financial arrangement is concluded. Finally, the National Health Care Institute is carrying out the second evaluation of the procedure, which will be presented to you in mid-2024.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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23 May 2024

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