BIRD
BELGIAN INFLAMMATORY BOWEL DISEASE RESEARCH AND DEVELOPMENT

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Dear colleague,

As you might know BIRD (Belgian IBD research and development group) is trying to engage more closely with the regulatory authorities over the last year. Accordingly, we want to improve the situation of the patients with IBD by simplifying the reimbursement criteria and improving the reimbursement administration for the physicians and IBD nurses. Recently we had a meeting with the board of the CTG/CRM from the RIZIV/INAMI on the mandatory use of CIVARS for reimbursement of vedolizumab (Entyvio). Subsequently, BIRD was also informed on new changes in the reimbursement for other advanced therapies in IBD. By this way we like to inform you as we feel that the current information flow is quite scattered and deficient.

Changes reimbursement ustekinumab for Crohn's disease (Stelara®)

- **From April 1st 2022** reimbursement for ustekinumab in bionaive patients with CD will be stopped (§ 8880000)
- New bionaive patients will have no access to ustekinumab from April 1th 2022 onwards.
- Reimbursement of ustekinumab in patients with CD is only possible in case of a severe flare of CD AND a prior treatment of minimal 3 months of anti-TNF or a documented intolerance or contra-indication.
- For this a new paragraph is created: § 11270000
- Bionaive patients with CD that received a reimbursement for ustekinumab prior to April 1th 2022 can continue their treatment. Only prolongation of § 8880000 is possible no first request from that time on.
- Bionaive patients that are currently in an induction treatment with ustekinumab need to submit the reimbursement request in § 8880000 before March 31th 2022.

Changes reimbursement infliximab/CT-P13 for Crohn's disease and ulcerative colitis (Flix-abi®, Inflectra®, Remicade®, Remsima®, Zessly®)

- **From March 1st 2022** for the reimbursement of infliximab/CT-P13 **IV** in **all** patients with IBD it is mandatory to follow the electronic notification pathway of CIVARS. This is the case for all paragraphs (independent of IV or SC maintenance) (https://idp.iamfas.belgium.be/fasui/_a00364f6cfc2e51c357c17925ae6b067)
- Patients with IBD that received a reimbursement for infliximab/CT-P13 **prior** to March 1th 2022 can continue their treatment. But a new electronic application is **mandatory** if they had reimbursement in § 1990000 (CD IV induction and maintenance trajectory) or § 3960000 (UC IV induction and maintenance trajectory). This request needs to be a "new request" in CIVARS as this has not been registered in *mycarenet*.
- A regularization period of 2 years is foreseen for this transition.
- Patients with IBD that received a reimbursement for infliximab/CT-P13 **prior** to March 1th 2022 in § 10500100 (CD IV induction and SC maintenance trajectory) or § 10490100 (UC IV induction and SC maintenance trajectory) need **no** new electronic application.
- In case of issues with a specific patient you can contact the CTG/CRM via CTGCRM.database@riziv-inami.fgov.be (National number patient, Name pharmaceutical speciality, Paragraph number, Indication first request or prolongation, Print screen error notification, Mutuality of the patient if available)

We understand these changes might have an important impact on the treatment of your patients and on the administrative burden of your practice. BIRD aims to further collaborate with the CTG/CRM to avoid these last minute changes and to lower the administrative burden. We reached out to the CTG/CRM and hope to proactively being able to optimize the reimbursement of specialities in IBD in the future.

Kind regards,

Dr Peter Bossuyt Secretary BIRD	Ms Eveline Hoefkens Chair Binastoria	Dr Filip Baert President BIRD