Swiss pre-approval process for pharmaceuticals and other medicinal products not covered by basic insurance: viewpoint of nephrologists

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Background

In Switzerland, the Federal Office of Public Health (FOPH) maintains lists of pharmaceuticals and other medicinal products that are covered by mandatory basic health or disability insurance. The inclusion of products on these lists is governed by considerations regarding effectiveness and costs. For medicinal products not on these lists, the health insurance may still reimburse their costs in individual cases provided certain conditions are met. This alternative process involves the treating physician submitting a pre-approval for cost reimbursement to the insurance provider before the start of treatment. Medical officers ("Vertrauensärzte") make a recommendation regarding the reimbursement of the product by the mandatory health insurance.

In nephrology, such requests for approval of certain medications or other products for individual patients are common, with anecdotal evidence suggesting that some nephrologists spend multiple hours per week on writing these requests and responses to their rebuttals. Moreover, the individualized approach raises equity concerns that similar requests for reimbursement might be dealt with differently by different health insurers, or even by different examiners within the same insurers. In order to more thoroughly examine these concerns, a project was developed to survey the experiences of different stakeholders (nephrologists, health insurers, Vertrauensärzte) to understand their experiences regarding the approval process.

Methods

An anonymous survey regarding experiences in applying for pre-approvals for specific medications, genetic testing and other interventions required for kidney disease care was distributed to 400 nephrologists in Switzerland between September 2021 and March 2022. Formal Ethics approval was not required. No personal or identifiable data was collected.

Questions centered around the following themes:

- Which medications/tests require pre-approval?
- How often are pre-approval requests denied?
- Are there inequities in denials of pre-approvals, within or between health insurers?
- What are Physician's experiences and opinions of the process?

Descriptive analysis and narrative reporting of experiences of the nephrologists regarding medication pre-approvals is presented here.

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Results

The survey was started by 94 participants, fully completed by 65. 43% of respondents were women, the majority were between 35 and 65 years of age, most were staff or senior physicians. 35% of respondents practice nephrology in adult University hospitals, 41% in adult B hospitals. Most respondents did not manage acute transplants (Fig. 1)

1. Responses regarding access to medication

The top 5 most contentious medications were Rituximab (reported by 54 respondents), SGLT2 inhibitors (34 respondents); Mycophenolate mofetil (28 respondents); Eculizumab (22 respondents) and Intravenous Immunoglobulin (15 respondents).

Rebuttals were required at least half of the time for these medications (Fig. 2). Overall, 37% and 51% of respondents reported that 51 – 75%, or 76 – 100% of requests respectively were eventually approved.

Strategies used to obtain medications when not approved are illustrated in Figure 3.

2. Equity of access to medications

- 88% of respondents reported that different insurers often/sometimes make different decisions for similar patients (Fig. 4).
- 43% reported that this was the case within insurers.

Thank you for participating!

Figure 1. Approximate proportion of respondent practice (n=94)

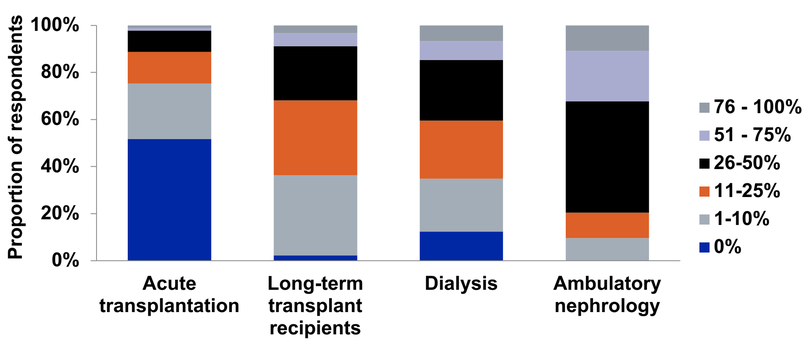


Figure 2. Frequency of need for rebuttal after first request for top 5 medications requiring pre-approval (n=70)

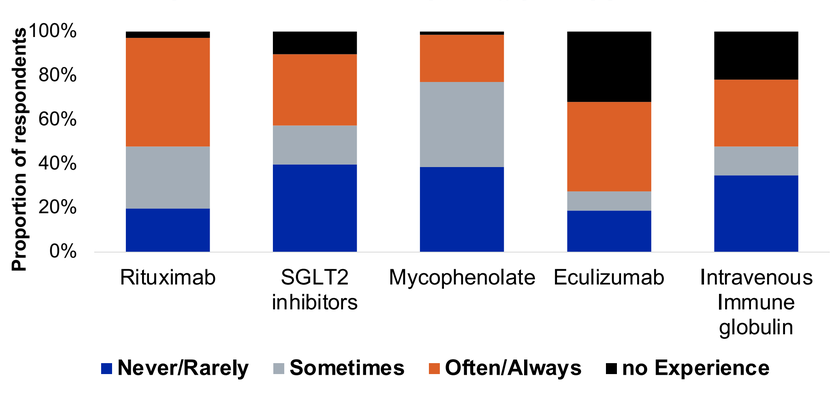


Figure 3. Frequencies of strategies used to obtain access to denied medications (n=71)

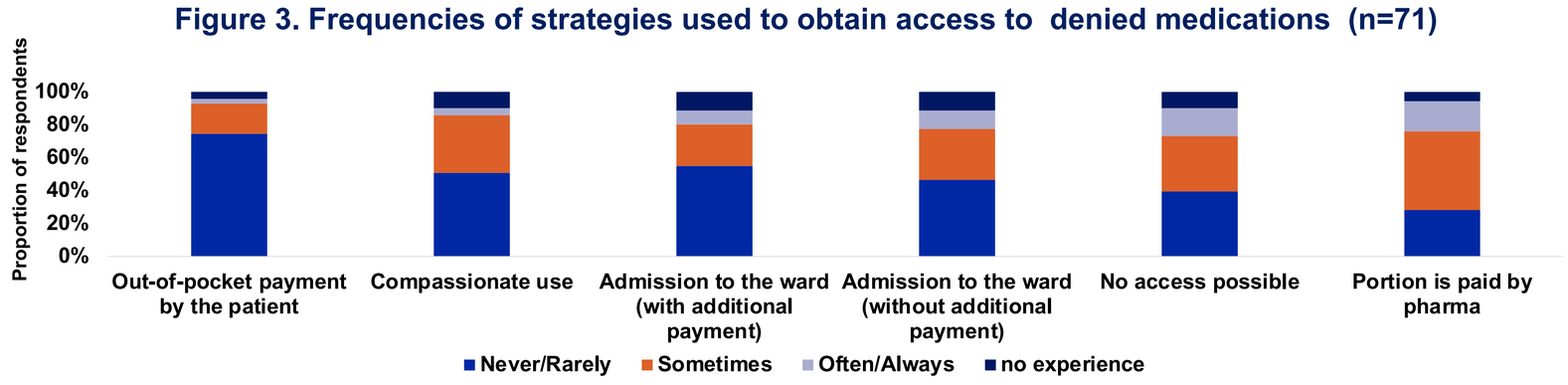
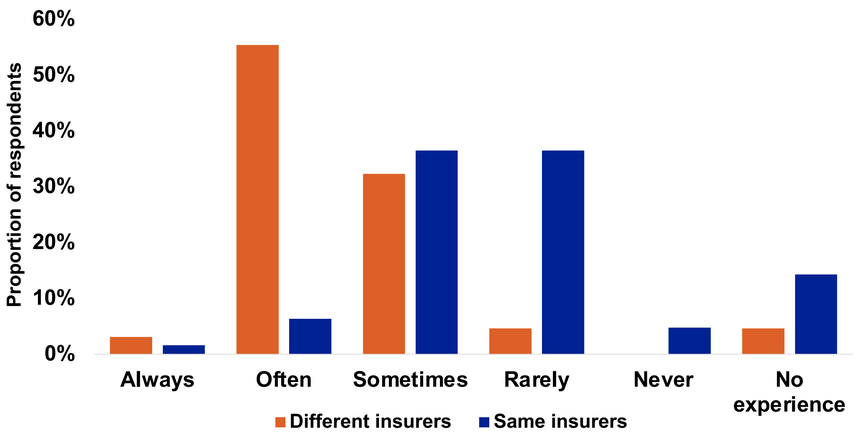


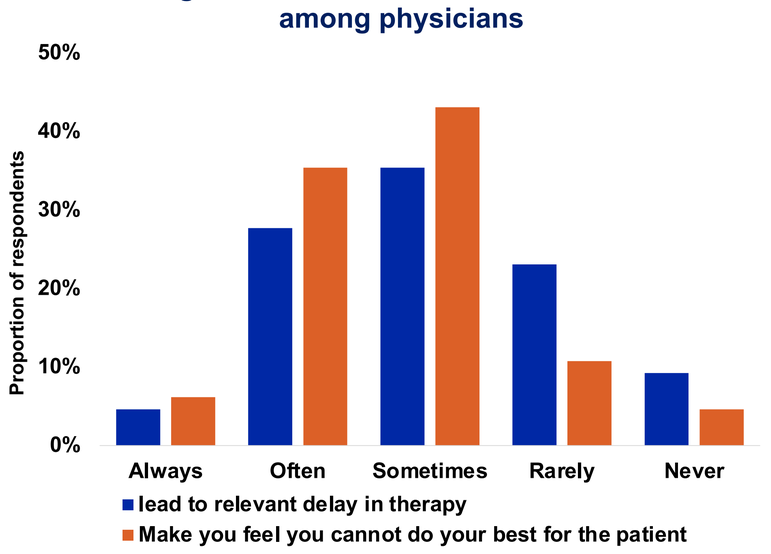
Figure 4. Frequency of different responses with the same or between different health insurers for similar patients/indications? (n=65)



3. Physicians experiences

- 59% of respondents reported that requests for further information from the health insurers were rarely/never reasonable.
- 72% of respondents reported rarely/never being able to engage directly with the medical officer at the health insurer.
- 97% reported sometimes/often/always being concerned that the medical officer did not have the required expertise to make a determination in the case.

Figure 5. Concern and moral distress among physicians



- 68% of respondents reported that the process led to clinically important delays in treatment always/often/sometimes (Fig. 5).
- 85% of respondents reported this process made them feel they could not do their best for their patients.

Conclusion

From the perspective of nephrologists, the pre-approval process in Switzerland is cumbersome, non-transparent and inequitable, and may result in denial or delays of important treatment for patients.

Work is needed to develop constructive, transparent and efficient solutions to facilitate this process for the patients and the physicians, in collaboration with all stakeholders.