

Leucopenia medicine and reimbursement code

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Introduction

The financing of the Austrian healthcare system by the Main Association of Austrian Social Security Institutions (HVB) differs with regard to the inpatient and outpatient sectors. For the inpatient sector, the HVB pays a case rate to hospitals to cover their medical services, including medicines, while for the outpatient sector, the HVB pays for medical attendance, medical devices and medicines that are listed in its reimbursement code. A separate HVB list includes medicines that are not paid for because they are administered predominantly in hospitals.

On 22 June 2018 the HVB refused to include Onpro Kit, a medicine for treating chemotherapy-induced leucopenia, in the reimbursement code. In its reasoning, the HVB qualified Onpro Kit as a medicine designated for hospital treatments. As chemotherapy is an inpatient treatment, the administration of Onpro Kit must also be attributed to the intramural sphere. Medicines designated for hospital treatments are excluded from the reimbursement code.

Decisions

In April 2019 the Federal Administrative Tribunal rejected an appeal by a patient against the HVB's decision.⁽¹⁾ The tribunal held that the HVB must establish a list of medicines that are, generally speaking, administered only in hospitals.

Following chemotherapy, Onpro Kit was administered to the patient. After approximately 27 hours, the Onpro Kit released an active ingredient by automatic injection. Therefore, the Onpro Kit had not been administered by a physician in a private practice, which is a precondition for inclusion in the reimbursement code.

On appeal, the Supreme Administrative Court set aside the tribunal's decision.⁽²⁾ The court held that 'medical treatment' comprises medical attendance by physicians in a private practice, medicines and medical devices. Further, medical treatment must be sufficient and appropriate (ie, not beyond what is medically necessary).⁽³⁾

The HVB must establish a reimbursement code for the administration of medicines in the outpatient sector. This code must include medicines with a marketing authorisation in Austria that are reimbursable, securely available and therapeutically effective according to the state of the art.

With regard to the list of non-reimbursable medicines for hospital treatments, the distinction between the allocation of costs for inpatient and outpatient treatments is decisive. The financing of the Austrian healthcare system provides that social security contributions for financing hospitals covers inpatient treatments. Medical service accounting is based on case rates, including all administered medicines during hospitalisation. In the outpatient sector, social security provides medical treatment as an in-kind benefit by panel doctors and panel pharmacies. These benefits in kind are paid according to social security tariffs. Accordingly, there is a distinction between the intramural ambulant sphere (hospitals) and extramural ambulant sphere (panel doctors). Not only is inpatient care part of the intramural sphere, but also services in hospital outpatient departments (eg, chemotherapy).

Medicines which can be administered in the extramural sphere (notwithstanding their predominant use in the intramural sphere) can also be reimbursed. The reason for using reimbursable criteria and the list established on that basis to determine the possibility of including a medicine in the reimbursement code is that the inclusion of a medicine which in practice is used only in the inpatient sector would be of little use and its cost would be ineligible for HVB reimbursement. The HVB need

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only pay the case rate for medicines used in hospitals and the reimbursement code does not apply. Further, regarding medicines used predominantly in hospitals, the HVB must assess if they can also be applied *lege artis* in the outpatient sector. If evidence shows that a medicine is also used in the outpatient sphere for medical treatment, it can be included in the reimbursement code subject to the HVB's prior approval of prescriptions.

Although the predominant use of a medicine for treatment in hospitals indicates its limited use for medical treatment in the outpatient sector, further evidence must be gathered if a *lege artis* administration of a treatment in the outpatient sector is appropriate (ie, not beyond what is medically necessary). If this evidence is provided, it may be eligible for HVB reimbursement.

According to the established facts, Onpro Kit is applied after chemotherapy in hospitals. This application to the patient's body constitutes the medicine's administration and not the automatic release more than 24 hours later. The administration of the medicine defers release of the active ingredient and saves the patient from having to revisit a hospital or a panel physician. Therefore, the application of Onpro Kit is intramural if the immediately preceding chemotherapy was also provided intramurally.

A medicine's administration in the outpatient sector therefore depends on whether the treatment (except for emergency situations) is also administered in the outpatient sector. In this case, the administration of the Onpro Kit is attributed to the outpatient sector, thereby affirming whether it is reimbursable. As the Federal Administrative Tribunal had established only that tumour therapies are provided in the inpatient sector, it would have had to assess whether outpatient chemotherapies were also available.

Comment

The Supreme Administrative Court's landmark decision provides further clarity on the inclusion of medicines in the reimbursement code. The court examined the special circumstances in which a medicine is inappropriate for use by a panel doctor in the course of medical treatment because it is designated for use predominantly in hospital treatments. The decisive factor is not a medicine's predominant application in the inpatient sector, but rather whether an appropriate and effective administration is also suitable in the outpatient sphere (financial considerations are thus also important when qualifying medicines).

Even if a medicine is listed in the reimbursement code, its administration is subject to prior approval by the HVB; if reimbursement is refused, the decision can be appealed to the social and labour courts.

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Endnotes

- (1) Federal Administrative Tribunal, 2 April 2019, W147 2201482-1/11E.
- (2) Supreme Administrative Court, 11 September 2019, RO 2019/08/0013.
- (3) Section 133(2) of the General Social Security Act.

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