



KRAJOWI PRODUCCENCI LEKÓW





**KRAJOWI
PRODUCENCI
LEKÓW**

Adalimumab retail reimbursement – EU examples

Austria

- **As a rule, biologics are available in the hospital channel. They have to be covered by the hospital budget, and this type of their use is not reimbursable by public sickness funds.**
- **In practice, hospital outpatient departments initiate the ADA therapy via outpatient prescriptions, which is covered by the sickness fund.**
- **The monitoring** is carried out based on the medical guidelines.
- **The patient treatment path** is in line with the clinical practice guidelines. The diagnosis, medicine prescription and regular check-ups are conducted by respective specialist physicians. The treatment does not require any additional approval from the NHF or any committee. The patient gets their prescription every month.
- **The patient co-payment** amounts to EUR 5-10. **The budget** has no cap. The costs are fully covered by the mandatory health insurance.



Belgium

- **Adalimumab and somatropin are available under the retail and hospital reimbursement.**
- **The therapy can be both initiated and maintained** by dermatology, rheumatology and gastroenterology specialists.
- **The monitoring** is carried out based on the medical guidelines.
- There is just one budget for medicines. All patients need to **co-pay** at the **maximum level of EUR 15 per pack**. Diagnostic tests pertaining to biological treatment are covered from a separate budget that is not related to medicines.



Germany

- **Biologics are available in hospitals and in pharmacies. The therapy is initiated at the hospital or pharmacy level. Hospitalised patients form a minor group.**
- **The therapy can be both initiated and maintained** by dermatology, rheumatology and gastroenterology specialists. **GPs are not involved in the process.**
- **The monitoring** is carried out based on the medical guidelines
- **The patient treatment path** is in line with the clinical practice guidelines. The diagnosis, medicine prescription and regular check-ups are conducted by respective specialist physicians. The treatment does not require any additional approval from the NHF or any committee. The patient gets their prescription every month.
- **Patients** covered by the state insurance bear the **payment of EUR 10. In the case of a chronic disease, the patient is exempted from the payment.**



Germany



DE Adalimumab sell-out packs in percent	Niemcy – Adalimumab opakowania w sell-out w wartościach procentowych
Office-based physicians	Lekarze leczący w gabinetach
Out-patient centers (retail pharmacy)	Przychodnie/poradnie (apteka otwarta)
Out-patient centers (hospital pharmacy)	Przychodnie/poradnie (apteka szpitalna)
Hospital in-patient	Pacjent hospitalizowany
Channel split	Podział kanałów



KRAJOWI PRODUCENCI LEKÓW

Bulgaria

- In Bulgaria, adalimumab is mainly available in the retail channel. It is also hospital available but that sector only accounts for less than 5% of adalimumab total sales.
- Biologics prescribed for oncology indications are always dispensed in hospitals. Yet if they are also indicated for some other, non-oncology conditions they can be prescribed for the outpatient use.
- For example, rituximab is hospital dispensed in its oncology indication and it is dispensed in retail pharmacies for the rheumatoid arthritis treatment.
- The biological therapy can be **initiated by physicians from selected clinical centres.**
- **The maintenance treatment can be conducted** by rheumatology and dermatology specialists.
- The National Health Insurance Fund has amended the criteria of prescribing and dispensing biologics several times. **Along with the entry of biosimilars, the criteria have turned less stringent,** given a lower therapy price.



Bulgaria

- **The monitoring** is based on the medical guidelines but also on the guidelines issued by the National Health Insurance Fund. **Patients should attend their monitoring visits in order to get a new prescription.**
- **The patient inclusion criteria to join biological treatment** are tantamount to the scientific guidelines. No additional administrative restrictions apply.
- All outpatient biologics are **75% reimbursable.**
- The Fund has a specific **budget allocated to the funding of retail available expensive medicinal products** (including biologics/biosimilars).



Croatia

- **Adalimumab was transferred from the hospital to retail reimbursement in July 2019.**
- **The change also applied to other immunology SC molecules.**
- **The first 4 months of treatment are conducted in the hospital channel.** The patient qualification for biosimilar treatment is approved by the hospital committee. Over that time, the patient receives all essential information concerning the product and its use, any possible adverse events, etc. Since the therapy evaluation usually takes place 12-16 weeks from the qualification the specialist physician evaluates the treatment outcomes and then recommends to continue the therapy (after the first 4 months) **in the pharmacy channel. The therapy continuation needs to be approved by the hospital committee.**
- Pharmacies dispense biosimilars to patients based on GP-issued prescriptions. **The prescription is based on the recommendation of the specialist physician, and the recommendation is approved by the hospital committee.**
- **The patient treatment inclusion and monitoring criteria** are in line with the clinical guidelines.
- **The product cost is 100% covered by the health insurance.** The diagnostic costs are borne by the hospital budget.



Estonia



- **Adalimumab was transferred from the hospital to retail reimbursement in June 2019.**
- **The change also applied to other immunology SC molecules.**
- The biological therapy **can be initiated** by specialist physicians working in hospitals – rheumatologists, dermatologists, gastroenterologists, and paediatricians.
- **The decision to start the treatment is taken by a committee consisting of 3 specialists.**
- **The maintenance treatment** can be conducted by specialist physicians.
- **The monitoring** is based on the medical guidelines. Rheumatologists have their own monitoring register. It is not available in the public domain. The Health Fund publishes its reports on a quarterly basis.
- **The patient co-payment** amounts to EUR 2.50 per prescription.
- There are two separate healthcare budgets, namely for the in- and outpatient treatment.



Finland

- **Adalimumab, etanercept, somatropin, and pegfilgrastim have been retail channel available since their marketing launch.**
- **The biological therapy can be initiated** by specialist physicians in hospitals and private healthcare clinics.
- **The maintenance therapy** can be conducted by GPs or specialists from any public or private healthcare clinic.
- **The monitoring** is carried out based on the medical guidelines.
- In some cases, specifically in the gastroenterology TA, the first doses are administered in hospitals, meaning that the medicines come from hospital resources. After the first injections, patients are referred to their retail pharmacy.
- There is no budget system in Finland. **Patients pay the maximum amount of EUR 627.66 per calendar year** for their reimbursable medicines. **If the said amount is exceeded all reimbursable medicines are free of charge** for the patient, apart from bearing some minor pharmacy fees if the medicine is collected from a pharmacy.



Lithuania

- **All biologics have been retail reimbursement available from the very beginning (adalimumab from April 2019).**
- **The initial and maintenance treatment** can be conducted by physicians from selected clinical centres and specialist physicians working in level III hospitals (top level in the hospital structure).
- **The monitoring** is carried out based on the medical guidelines.
- **The patient treatment path** is in line with the clinical practice guidelines.
- **Patients bear no payment. 100% product reimbursement.**
- In Lithuania, the retail price of reimbursable medicines results from the base price (part of the price that can be partly or fully covered by the sickness fund) and patient co-payment. If the base price is fully covered by the sickness fund such a case is considered as 100% reimbursement (as in the case of adalimumab). Still, patients may continue to co-pay (not more than EUR 4.71).



Latvia

- In Latvia, biologics are in 99% retail available. Some minor quantities of those medicines, accounting for around 1%, are acquired by hospitals in tenders. The rationale behind that practice is to have the medicines ready in hospitals in case of some specific circumstances, yet not for any regular treatment.
- The treatment can be **initiated** in selected clinical centres.
- **The maintenance treatment** can be conducted by physicians from selected clinical centres, physicians from all hospitals and specialist physicians from outpatient centres.
- **The monitoring** is carried out based on the medical guidelines.
- **The patient treatment path** is in line with the clinical practice guidelines.
- **Patients bear no payment. 100% product reimbursement.**



Slovakia

- **In Slovakia, adalimumab is available (and reimbursable) in hospital pharmacies, specialist centres as well as in retail pharmacies since the molecule is included in the reimbursement list.**
- **The initial and maintenance treatment** can be conducted by specialist physicians, i.e. dermatologists, gastroenterologists and rheumatologists.
- Physicians from outpatient clinics did not have any experience in the biological treatment initiation before the marketing launch of biosimilar adalimumab.
- Before the biosimilar launch, the adalimumab treatment was only possible in some specialist centres.
- There are no specific requirements as regards the **monitoring**.
- **The treatment needs to be preceded by its health insurance approval.** The procedure needs to be repeated every six months.
- **100% reimbursement.**



Slovenia

- **Some biologics are available in the retail channel, in the retail and hospital channels, and some only in the hospital channel.**
- As regards adalimumab, the treatment can be **initiated by physicians from selected hospitals and wards**. The selection is conducted by the Fund. There are only few cases (dermatology centres and one gastroenterology centre) of physicians from outpatient clinics to have the right to prescribe adalimumab. It is mainly due to the fact that there are few outpatient clinics in Slovenia.
- **The maintenance treatment** is conducted by physicians from selected clinical centres.
- The outpatient dermatology centres had experience in the initiation of biological therapies before the marketing launch of biosimilars.
- **The monitoring** is carried out based on the clinical practice guidance and guidelines.
- **The inclusion criteria to join biological therapies** are in line with the clinical practice guidelines. The diagnostic and medicine prescription are conducted by the specialist physician. There is no need to obtain any additional permits or approvals.
- **The therapy cost is fully covered by the NHF.**



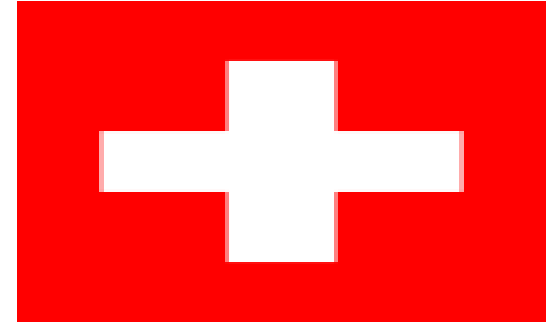
Sweden

- **Adalimumab has been retail reimbursement available since its marketing launch.**
- The treatment can be **initiated** by specialist physicians in hospitals or private healthcare centres.
- **The maintenance treatment** is conducted by GPs or by specialists in any public or private healthcare centre.
- **The monitoring** is carried out based on the clinical practice guidance and guidelines.
- **The inclusion criteria to join biological therapies** are in line with the clinical practice guidelines.
- **The National Reimbursable Medicines Budget, including biologics, has been established**, yet it is every region that takes responsibility for its use.
- **Patients pay the maximum of EUR 220** per year for the medicines available under the reimbursement system.



Switzerland

- **Both adalimumab and all other biologics (biosimilars) are available in hospitals, in outpatient centres and in pharmacies against prescription.**
- Both treatment stages (**initial and maintenance therapy**) are conducted by dedicated specialist physicians (rheumatologists, gastroenterologists, dermatologists, and oncologists) irrespective of the fact whether they take place in hospital or in outpatient centre. No GPs are involved.
- Physicians from outpatient centres initiated biological therapies (with originators) in the past. No issues were found as all physicians were experienced.
- **The monitoring** is carried out according to the domestic guidelines, at the physician's discretion.
- The medicine is reimbursable as the **second line therapy** after the use of classic medicines.
- **10% of patient co-payment** up to CHF 700.



Romania

- The majority of biologics are retail pharmacy available.
- There are three molecules available both in the hospital (H) and in the retail (R) channel:
 - Pegfilgrastim (H – 5%; R – 95%);
 - Filgrastim (H – 30%; R – 70%);
 - Rituximab – oncology is based on H (90%) and rheumatology is based on R (10%) – in this case it is very likely that the MoH will come back to the national tender model.
- Both treatment stages (**initial and maintenance therapy**) are conducted by specialist physicians, irrespective whether they work in hospitals or outpatient centres, after having obtained the recommendation from the specialist working in a large university hospital.
- **The monitoring** is carried out according to the domestic guidelines.
- The medicine is reimbursable as the **second line therapy** after the use of classic medicines.
- **The Ministry of Health reimburses 120% of the lowest price.**



France

- **Adalimumab (as well as other biologics) is available both under the retail and hospital reimbursement schemes (1% in hospitals).**
- **Other biologics are mainly available in retail against prescription (except for, for instance, infliximab).**
- **At the stage of therapy initiation,** adalimumab can only be prescribed by hospital specialists (from any clinical centre or hospital).
- **The maintenance therapy** can be conducted by any specialist physician from hospital or outpatient centres.
- **The initiation** needs to take place in hospital conditions, and then the patient can collect their adalimumab in retail pharmacies for self-injection (pen) or for injection to be conducted by a nurse at the patient's. Physicians can re-issue the prescription.
- **The monitoring** is carried out based on the medical guidelines, and the patient has to receive the patient monitoring card that contains a note stating that adalimumab treatment can increase the risk of infections and cancer development.
- Adalimumab is **at least 65% reimbursable**, with the remaining 35% being covered by supplementary health insurances. Yet the majority of adalimumab indications are **chronic conditions in which case 100% of the cost is covered by the healthcare system.**

