

Resolution
by the Federal Joint Committee
on an amendment to the Pharmaceutical Directive (AM-RL):
Appendix XII – Resolutions on the benefit assessment of pharmaceuticals with new active ingredients,
in accordance with the German Social Code, Book Five (SGB V), section 35a
Bromfenac
from 19 January 2012

In its session on 19 January 2012, the Federal Joint Committee resolved to amend the Pharmaceutical Directive (AM-RL), version published 18 December 2008/22 January 2009 (Federal Gazette number 49a of 31 March 2009), last amended on 15 December 2011 (Federal Gazette, 2012, page 490), as follows:

I.

Appendix XII shall be amended in alphabetical order to include the following active ingredient:

Bromfenac

Therapeutic indication:

Yellox® is indicated for the treatment of postoperative ocular inflammation following cataract extraction in adults.

1. Additional benefit of the pharmaceutical over appropriate comparative treatment

Treatment of post-operative ocular inflammation following cataract extraction in adults:

Appropriate comparator: Dexamethasone eye drops

Extent and probability of additional benefit: An additional benefit over the appropriate comparator in accordance with SGB V, section 35a, paragraph 1, sentence 5 has not been proved.

2. Number of patients and criteria for defining patients eligible for treatment

Cataract surgeries in Germany:

Number: 850,000–1,000,000 eyes operated

3. Requirements for quality-assured administration

No particular requirements for quality-assured administration are noted in the product information on Yellox®.

4. Costs of treatment

("Lauer-Taxe", effective 1 January 2012)

Treatment of post-operative ocular inflammation following cataract extraction in adults:

Duration of treatment:

Description of therapy	Mode of treatment	Number of treatments per eye operated and year	Duration per treatment (days)	Treatment days per eye operated and year ¹
Bromfenac (Yellox®)	ongoing, 2 x daily 1 drop per eye	1	14	14
Dexamethason eye drops (e.g. Dexapos®)	ongoing, 3–5 x daily 1 drop per eye	1	14	14

¹ under the condition that only one treatment is necessary; use for more than 14 days is not recommended according to product information

Consumption:

Description of therapy	Strength (mg)	Number/amount per pack ¹	Average annual consumption one pack ¹
Bromfenac	0.9 mg/ml	5 ml	5 ml
Dexamethasone (Dexamethasone-21-(3-sulfobenzoate), sodium salt)	1 mg/ml	5 ml	5 ml

¹ each pack, sufficient for one therapy cycle

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Bromfenac	€24.53	€20.70 Discount in accordance with SGB V, section 130, paragraph 1: €2.05 Discount in accordance with SGB V, section 130a, paragraph 1a: €1.78 (16%)
Dexamethasone ¹	€13.59	€11.15 Discount in accordance with SGB V, section 130, paragraph 1: €2.05 Discount in accordance with SGB V, section 130a, paragraph 3b: €0.39 (16%)

¹ Lowest-cost preparation (Dexapos®)

Costs for additional, necessary statutory health insurance (SHI) benefits:

Description of therapy	Description of additional SHI expense item	Number of additional necessary SHI expense items per episode, cycle, etc.	Number of additional necessary SHI expense items per patient per year	Cost per unit
none	none	none	none	none

Annual treatment costs:

Description of therapy	Annual treatment costs per eye operated (Cost after legally mandated rebates)
Bromfenac	€20.70
Dexamethasone	€11.15

II.

This amendment takes effect on the day after its publication in the Federal Gazette.

The justification for this resolution will be published on the website of the Federal Joint Committee at www.g-ba.de.

Berlin, 19 January 2012

The Federal Joint Committee in
accordance with SGB V,
section 91
The Chair
Hess