Gemeinsamer Bundesausschuss

Filgotinib

Resolution of: 15 April 2021 valid until: unlimited
Entry into force on: 15 April 2021
BAnz AT 04.06.2021 B3

Therapeutic indication (according to the marketing authorisation of 24 September 2020):

Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an inadequate response to or are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Jyseleca can be used as monotherapy or in combination with methotrexate (MTX).

Therapeutic indication of the resolution (resolution from the 15/04/2021):

see therapeutic indication according to marketing authorisation

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

a1) Adult patients with moderate to severe active rheumatoid arthritis who do not have poor prognostic factors [1] and who have had an inadequate response to, or were intolerant to previous treatment with a disease-modifying anti-rheumatic drugs (classical DMARDs, including methotrexate (MTX)); filgotinib monotherapy

Appropriate comparator therapy:

Alternative classical DMARDs, if suitable (MTX, leflunomide, sulfasalazine) as mono or combination therapy

Extent and probability of the additional benefit of filgotinib as monotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven

a2) Adult patients with moderate to severe active rheumatoid arthritis who do not have poor prognostic factors[1] and who have had an inadequate response to, or were intolerant to previous treatment with a disease-modifying anti-rheumatic drugs (classical DMARDs, including methotrexate (MTX)); filgotinib in combination with MTX

Appropriate comparator therapy:

[1] Poor prognostic factors:
- Detection of autoantibodies (e.g. rheumatoid factors, high levels of antibodies against citrullinated peptide antigens)
- High disease activity (detected by DAS or DAS28 score, swollen joints, acute phase reaction parameters such as C-reactive protein, erythrocyte sedimentation rate)
- Early occurrence of joint erosions

Alternative classical DMARDs, if suitable (MTX, leflunomide, sulfasalazine) as mono- or combination therapy

Extent and probability of the additional benefit of filgotinib + MTX compared to the appropriate comparator therapy:

An additional benefit is not proven

b1.) Adult patients with moderate to severe active rheumatoid arthritis for whom initial therapy with biotechnology DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated; filgotinib as monotherapy

Appropriate comparator therapy:

bDMARDs or tsDMARDs (abatacept or adalimumab or baricitinib or certolizumab pegol or etanercept or golimumab or infliximab or sarilumab or tocilizumab or tofacitinib or upadacitinib) in combination with MTX; if necessary as monotherapy taking into account the respective authorisation status in case of MTX intolerance or unsuitability

Extent and probability of the additional benefit of filgotinib as monotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven

b2) Adult patients with moderate to severe active rheumatoid arthritis for whom initial therapy with biotechnology DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated; filgotinib in combination with MTX

Appropriate comparator therapy:

bDMARDs or tsDMARDs (abatacept or adalimumab or baricitinib or certolizumab pegol or etanercept or golimumab or infliximab or sarilumab or tocilizumab or tofacitinib or upadacitinib) in combination with MTX

Extent and probability of the additional benefit of filgotinib + MTX compared to adalimumab + MTX:

Hint for a minor additional benefit

c1) Adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to, or have been intolerant to previous treatment with one or more bDMARDs and/or tsDMARDs; filgotinib monotherapy

Appropriate comparator therapy:

Change of bDMARD or tsDMARD therapy (abatacept or adalimumab or baricitinib or certolizumab pegol or etanercept or golimumab or infliximab or sarilumab or tocilizumab or tofacitinib or upadacitinib, in combination with MTX; if applicable. as monotherapy, taking into account the respective marketing authorisation status in the case of MTX intolerance or unsuitability; or in patients with severe rheumatoid arthritis, rituximab, taking into account the marketing authorisation status) depending on the previous therapy.

Extent and probability of the additional benefit of filgotinib as monotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven

c2) Adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to, or have been intolerant to previous treatment with one or more bDMARDs and/or tsDMARDs; filgotinib in combination with MTX

Appropriate comparator therapy:

Change of bDMARD or tsDMARD therapy (abatacept or adalimumab or baricitinib or certolizumab pegol or etanercept or golimumab or infliximab or sarilumab or tocilizumab or tofacitinib or upadacitinib, in combination with MTX; or in patients with severe rheumatoid arthritis, rituximab, taking into account the respective marketing authorisation status) depending on previous therapy.

Extent and probability of the additional benefit of filgotinib + MTX compared to the appropriate comparator therapy:

An additional benefit is not proven

Study results according to endpoints:[2]

a1) Adult patients with moderate to severe active rheumatoid arthritis who do not have poor prognostic factors[1] and who have had an inadequate response to, or were intolerant to previous treatment with a disease-modifying anti-rheumatic drugs (classical DMARDs, including methotrexate (MTX)); filgotinib monotherapy

No data submitted.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	No data submitted.
Morbidity	∅	No data submitted.
Health-related quality of life	∅	No data submitted.
Side effects	∅	No data submitted.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: There are no usable data for the benefit assessment.
n.a. not assessable

a2) Adult patients with moderate to severe active rheumatoid arthritis who do not have poor prognostic factors[1] and who have had an inadequate response to, or were intolerant to

[2] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A20-08) unless otherwise indicated.

previous treatment with a disease-modifying anti-rheumatic drugs (classical DMARDs, including methotrexate (MTX)); filgotinib in combination with MTX

No data submitted.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	No data submitted.
Morbidity	∅	No data submitted.
Health-related quality of life	∅	No data submitted.
Side effects	∅	No data submitted.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅ : There are no usable data for the benefit assessment. n.a. not assessable		

b1.) Adult patients with moderate to severe active rheumatoid arthritis for whom initial therapy with biotechnology DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated; filgotinib as monotherapy

No data submitted.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	No data submitted.
Morbidity	∅	No data submitted.
Health-related quality of life	∅	No data submitted.
Side effects	∅	No data submitted.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅ : There are no usable data for the benefit assessment. n.a. not assessable		

b2) Adult patients with moderate to severe active rheumatoid arthritis for whom initial therapy with biotechnology DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated; filgotinib in combination with MTX

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	↑	Advantages in remission and low disease activity.
Health-related quality of life	↔	No relevant difference for the benefit assessment.
Side effects	↔	No relevant difference for the benefit assessment.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

FINCH 1 study: RCT filgotinib + methotrexate (MTX) vs adalimumab + MTX (data cut-off to week 52)

Mortality

Study FINCH1 Endpoint	Filgotinib + MTX		Adalimumab + MTX		Filgotinib + MTX vs Adalimumab + MTX
	N	Patients with event	N	Patients with event	RR [95% CI] p value

		n (%)		n (%)	
Total mortality	475	3 (0.6)	325	1 (0.3)	2.05 [0.21; 19.65]; 0.53

Morbidity

Study FINCH1 Endpoint	Filgotinib + MTX		Adalimumab + MTX		Filgotinib + MTX vs Adalimumab + MTX
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
clinical remission					
CDAI ≤ 2.8					
NRI	475	140 (29.5)	325	74 (22.8)	1.29 [1.02; 1.64]; 0.035[a, b]
Sensitivity analysis: NRI with variance correction	475	140 (29.5)	325	74 (22.8)	1.29 [0.99; 1.69]; 0.060[c, d]
Sensitivity analysis: ACA[e]	399	140 (35.1)	265	74 (27.9)	1.26 [0.99; 1.59]; 0.057[c]
Sensitivity analysis ICA-pc with variance correction[f]	475	---(33.9)	325	---(27.9)	1.22 [0.96; 1.54]; 0.107[c, d]
SDAI ≤ 3.3					
NRI	475	141 (29.7)	325	78 (24.0)	1.24 [0.98; 1.56]; 0.074[g, h]
boolean definition					
NRI	475	107 (22.5)	325	55 (16.9)	1.34 [1.00; 1.79]; 0.047[g, h]
low disease activity					
CDAI ≤ 10	475	318 (66.9)	325	199 (61.2)	1.09 [0.98; 1.21]; 0.11[a, b]
SDAI ≤ 11	475	320 (67.4)	325	195 (60.0)	1.12 [1.01; 1.24];

Study FINCH1 Endpoint	Filgotinib + MTX		Adalimumab + MTX		Filgotinib + MTX vs Adalimumab + MTX
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
					0.039 [g, h]
DAS 28 (CRP) ≤ 3.2 (presented additionally)	475	313 (65.9)	325	191 (58.8)	1.12 [1.00; 1.25]; 0.041[g, h]
Pain (VAS)					
Improvement by ≥ 15 mm or points (corresponds to 15% of the scale span)	475	329 (69.3)	325	217 (66.8)	1.03 [0.94; 1.14]; 0.48[a, b]
patient-reported assessment of disease activity (VAS)					
Improvement by ≥ 15 mm or points (corresponds to 15% of the scale span)	475	348 (73.3)	325	223 (68.6)	1.06 [0.97; 1.16]; 0.22[a, b]
physical functional status (HAQ-DI)[3]					
Improvement of ≥ 0.45 points (corresponds to 15 % of the scale range)	475	305 (64.2)	325	183 (56.3)	1.12 [1.00; 1.25]; 0.054[a, b]
Improvement by ≥ 0.22 points	475	348 (73.3)	325	222 (68.3)	1.07 [0.98; 1.17]; 0.11 [g, h]
Fatigue (FACIT-Fatigue)[3]					
Improvement of ≥ 7.8 points (corresponds to 15 % of the scale range)	475	239 (50.3)	325	156 (48.0)	1.04 [0.90; 1.20]; 0.62 [a, b]

[3] Against the background of the current methodological discussion, both evaluations are presented here.

Study FINCH1 Endpoint	Filgotinib + MTX		Adalimumab + MTX		Filgotinib + MTX vs Adalimumab + MTX
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Improvement by ≥ 4 points	475	300 (63.2)	325	191 (58.8)	1.07 [0.96; 1.20]; 0.22 [g, h]
Health status (EQ-5D VAS)					
Improvement by ≥ 15 mm or points (corresponds to 15% of the scale span)	475	254 (53.5)	325	167 (51.4)	1.02 [0.89; 1.17]; 0.75 [a, b]

Study FINCH1 Endpoint scale	Filgotinib + MTX			Adalimumab + MTX			Filgotinib + MTX vs Adalimumab + MTX
	N[i]	Values at start of study MV (SD)	Change to week 52 MV (SD)	N[i]	Values at start of study MV (SD)	Change to week 52 MV (SD)	MD RR [95% CI]; p value[j]
Joint status							
joints painful under pressure[k]	400	11 (5.2)	-10 (5.1)	265	11 (5.0)	-10 (4.7)	0 [-1; 0]; 0,013
swollen joints[k]	400	15 (6.4)	-13 (6.0)	265	15 (6.3)	-12 (5.8)	-1 [-1; 0]; 0.014

Health-related quality of life

Study SELECT COMPARE Endpoint	Filgotinib + MTX		Adalimumab + MTX		Filgotinib + MTX vs Adalimumab + MTX
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value [g, h]
SF-36 (improvement of ≥ 5 points)[3]					
physical sum score	475	320 (67.4)	325	211 (64.9)	1.03 [0.93; 1.14]; 0.56 [g, h]
psychic sum score	475	220 (46.3)	325	144 (44.3)	1.04 [0.89; 1.21]; 0.63 [g, h]

Side effects

Study FINCH1 Endpoint	Filgotinib + MTX		Adalimumab + MTX		Filgotinib + MTX vs Adalimumab + MTX
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
AEs (presented additionally)	475	352 (74.1)	325	239 (73.5)	–
SAEs	475	35 (7.4)	325	22 (6.8)	1.09 [0.65; 1.82]; 0,75
Discontinuation because of AEs	475	26 (5.5)	325	18 (5.5)	0.99 [0.55; 1.77]; 0.97
Infections (SOC, AE)	475	206 (43.4)	325	129 (39.7)	1.09 [0.92; 1.29]; 0,30
serious infections (SOC, SAE)	475	13 (2.7)	325	10 (3.1)	0.89 [0.39; 2.00]; 0,78

a. Effect estimation based on a generalised linear model (GLM) with treatment group and stratification factors
b. Replacement strategy NRI: Patients with missing values or after discontinuation of study medication are assessed as non-responders
c. IQWiG's own calculation, asymptotic
d. IQWiG's own calculation, variance estimation according to the Data Set Re-Sizing Approach (Approach W3 in "Higgins JPT, White IR, Wood AM. Imputation methods for missing outcome data in meta-analysis of clinical trials. Clin Trials 2008; 5(3): 225-239. ")
e. Evaluation based exclusively on fully observed patients
f. In both treatment groups, the missing values are replaced according to the observed risk in the control group.
g. Effect estimation based on a generalised linear model (GLM) with treatment group and stratification factors
h. Missing values and values after discontinuation of study medication are replaced by means of NRI.
i. Number of patients with value at week 52; values at start of study may be based on other patient numbers.
j. Effect estimate based on MMRM analysis with baseline, treatment group, and visits as categorical variables, stratification factors, and treatment interaction*visit as fixed effect and patients as random effect
k. based on 28 joints
l. Higher values mean better health-related quality of life; a positive group difference means an advantage for filgotinib + MTX.

ACA: Available Case Analysis; CDAI: Clinical Disease Activity Index; CRP: C-reactive protein; DAS28: DAS based on 28 joints; EQ-5D: European Quality of Life Questionnaire - 5 Dimensions; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy - Fatigue; GLM: generalised linear models; HAQ-DI: Health Assessment Questionnaire - Disability Index; ICA-pc: Imputed case analysis according to risk in the control group; CI: Confidence interval; MD: Mean difference; MI: multiple imputation; min: Minutes; MTX: Methotrexate; MV: Mean; MD: Mean difference; MMRM: mixed model with repeated measures; n: number of patients with (at least 1) event; N: Number of patients evaluated; NRI: Non-responder imputation; RCT: randomised controlled trial; RR: relative risk; SDAI: Simplified Disease Activity Index; SD: Standard deviation; SF-36: Short Form-36 Health Survey; SOC: System organ class; SAE: serious adverse event; AE: adverse event; VAS: visual analogue scale; vs: versus.

c1) Adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to, or have been intolerant to previous treatment with one or more bDMARDs and/or tsDMARDs; filgotinib monotherapy

No data submitted.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	No data submitted.
Morbidity	∅	No data submitted.
Health-related quality of life	∅	No data submitted.
Side effects	∅	No data submitted.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
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↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅ : There are no usable data for the benefit assessment.
n.a. not assessable

c2) Adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to, or have been intolerant to previous treatment with one or more bDMARDs and/or tsDMARDs; filgotinib in combination with MTX

No data submitted.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	No data submitted.
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2. Number of patients or demarcation of patient groups eligible for treatment

a) Adult patients with moderate to severe active rheumatoid arthritis who do not have poor prognostic factors[1] and who have had an inadequate response to, or were intolerant to, previous treatment with a disease-modifying anti-rheumatic drugs (classical DMARDs, including methotrexate (MTX))(a1+a2)

approx. 14.150 to 39.350 patients

b) Adult patients with moderate to severe active rheumatoid arthritis for whom initial therapy with biotechnology DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated (b1+b2)

approx. 58.980 to 127.630 patients

c) Adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to, or have not tolerated, previous treatment with one or more bDMARDs and/or tsDMARDs (c1+c2)

approx. 16.600 to 26.860 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Jyseleca (active ingredient: filgotinib) at the following publicly accessible link (last access: 06 January 2021):
https://www.ema.europa.eu/documents/product-information/jyseleca-epar-product-information_de.pdf

In accordance with the requirements of the European Medicines Agency (EMA) regarding additional risk minimisation measures, the pharmaceutical company must provide training material and a patient identification card. The training material for medical professionals includes instructions on how to manage the potential side effects associated with filgotinib, particularly severe and opportunistic infections including TB and herpes zoster and the risk for impaired spermatogenesis. The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. The reversibility of these potential effects is not known. The potential risk of decreased fertility or infertility should be discussed with male patients prior to initiation of treatment.

Therapy should be started by a doctor experienced in the diagnosis and treatment of rheumatoid arthritis.

The use of the drug must also be carefully weighed against established therapies against the background of a comparatively new mode of action and the associated still existing uncertainties in the risk profile.

4. Treatment costs

Annual treatment costs:

Adult patients with moderate to severe active rheumatoid arthritis who do not have poor prognostic factors[1] and who have had an inadequate response to, or were intolerant to, previous treatment with a disease-modifying anti-rheumatic drugs (classical DMARDs, including methotrexate (MTX)); filgotinib monotherapy

Designation of the therapy	Annual treatment costs per patient
Medicinal product to be assessed:	
Filgotinib additionally required SHI services Total	€ 15,046.84 € 180.64 € 15,227.48
Appropriate comparator therapy for patient population a1	
Methotrexate	€ 51.98 – € 129.14
Leflunomide	€ 601.41 – € 939.07
Sulfasalazine	€ 345.05 – € 517.57

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 March 2021).

a2) Adult patients with moderate to severe active rheumatoid arthritis who do not have poor prognostic factors[1] and who have had an inadequate response to, or were intolerant to

previous treatment with a disease-modifying anti-rheumatic drugs (classical DMARDs, including methotrexate (MTX)); filgotinib in combination with MTX

Designation of the therapy	Annual treatment costs per patient
Medicinal product to be assessed:	
Filgotinib Methotrexate additionally required SHI services Total	€ 15,046.84 € 51.98 – € 129.14 € 180.64 €15,279.46 – €15,356.62
Appropriate comparator therapy for patient population a2	
Methotrexate	€ 51.98 – € 129.14
Leflunomide	€ 601.41 – € 939.07
Sulfasalazine	€ 345.05 – € 517.57

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 March 2021).

b1.) Adult patients with moderate to severe active rheumatoid arthritis for whom initial therapy with biotechnology DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated; filgotinib as monotherapy

Designation of the therapy	Annual treatment costs per patient
Medicinal product to be assessed:	
Filgotinib additionally required SHI services Total	€ 15,046.84 € 106.40 € 15,153.24
Appropriate comparator therapy for patient population b1	
Abatacept Methotrexate additionally required SHI services Total	€ 18,930.06 € 51.98 – € 129.14 € 106.40 €19,088.44 – €19,165.60
Adalimumab additionally required SHI services Total	€ 11,510.06 € 106.40 € 11,616.46
Adalimumab Methotrexate additionally required SHI services Total	€ 11,510.06 € 51.98 – € 129.14 € 106.40 € 11,668.44 – € 11,745.60
Baricitinib additionally required SHI services Total	€ 14,328.26 € 106.40 € 14,434.66
Baricitinib Methotrexate additionally required SHI services Total	€ 14,328.26 € 51.98 – € 129.14 € 106.40 € 14,486.64 – € 14,563.80
Certolizumab pegol additionally required SHI services	€ 19,808.29 € 106.40

Designation of the therapy	Annual treatment costs per patient
Total	€ 19,914.69
Certolizumab pegol Methotrexate additionally required SHI services Total	€ 19,808.29 € 51.98 – € 129.14 € 106.40 € 19,966.67 – € 20,043.83
Etanercept additionally required SHI services Total	€ 16,885.18 € 106.40 € 16,991.58
Etanercept Methotrexate additionally required SHI services Total	€ 16,885.18 € 51.98 – € 129.14 € 106.40 € 17,043.56 – € 17,120.72
Golimumab Methotrexate additionally required SHI services Total	€ 20,974.88 € 51.98 – € 129.14 € 106.40 € 21,133.26 – € 21,210.42
Infliximab Methotrexate additionally required SHI services Total	€ 12,512.92 – € 25,025.83 € 51.98 – € 129.14 € 106.40 € 12,671.30 – € 25,261.37
Sarilumab	€ 17,299.30
Sarilumab Methotrexate Total	€ 17,299.30 € 51.98 – € 129.14 € 17,351.28 – € 17,428.44
Tocilizumab	€ 22,433.52
Tocilizumab Methotrexate Total	€ 22,433.52 € 51.98 – € 129.14 €22,485.50– €22,562.66
Tofacitinib additionally required SHI services Total	€ 12,565.79 € 106.40 €12,672.19
Tofacitinib Methotrexate additionally required SHI services Total	€ 12,565.79 € 51.98 – € 129.14 € 106.40 €12,724.17 – €12,801.33
Upadacitinib additionally required SHI services Total	€ 15,056.17 € 106.40 € 15,162.57
Upadacitinib Methotrexate additionally required SHI services Total	€ 15,056.17 € 51.98 – € 129.14 € 106.40 € 15,214.55 – € 15,291.71

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 March 2021).

b2) Adult patients with moderate to severe active rheumatoid arthritis for whom initial therapy with biotechnology DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs) is indicated; filgotinib in combination with MTX

Designation of the therapy	Annual treatment costs per patient
Medicinal product to be assessed:	
Filgotinib Methotrexate additionally required SHI services Total	€ 15,046.84 € 51.98 – € 129.14 € 106.40 €15,205.22 – €15,282.38
Appropriate comparator therapy for patient population b2	
Abatacept Methotrexate additionally required SHI services Total	€ 18,930.06 € 51.98 – € 129.14 € 106.40 € 19,088.44 – € 19,165.60
Adalimumab Methotrexate additionally required SHI services Total	€ 11,510.06 € 51.98 – € 129.14 € 106.40 € 11,668.44 – € 11,745.60
Baricitinib Methotrexate additionally required SHI services Total	€ 14,328.26 € 51.98 – € 129.14 € 106.40 € 14,486.64 – € 14,563.80
Certolizumab pegol Methotrexate additionally required SHI services Total	€ 19,808.29 € 51.98 – € 129.14 € 106.40 € 19,966.67 – € 20,043.83
Etanercept Methotrexate additionally required SHI services Total	€ 16,885.18 € 51.98 – € 129.14 € 106.40 € 17,043.56 – € 17,120.72
Golimumab Methotrexate additionally required SHI services Total	€ 20,974.88 € 51.98 – € 129.14 € 106.40 €21,133.26 – €21,210.42
Infliximab Methotrexate additionally required SHI services Total	€ 12,512.92 – € 25,025.83 € 51.98 – € 129.14 € 106.40 € 12,671.30 – € 25,261.37
Sarilumab Methotrexate Total	€ 17,299.30 € 51.98 – € 129.14 € 17,351.28 – € 17,428.44
Tocilizumab Methotrexate Total	€ 22,433.52 € 51.98 – € 129.14 € 22,485.50 – € 22,562.66
Tofacitinib Methotrexate additionally required SHI services Total	€ 12,565.79 € 51.98 – € 129.14 € 106.40 € 12,724.17 – €12,801.33

Designation of the therapy	Annual treatment costs per patient
Upadacitinib Methotrexate additionally required SHI services Total	€ 15,056.17 € 51.98 – € 129.14 € 106.40 € 15,214.55 – € 15,291.71

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 March 2021).

c1) Adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to, or have been intolerant to, previous treatment with one or more bDMARDs and/or tsDMARDs; filgotinib as monotherapy

Designation of the therapy	Annual treatment costs per patient
Medicinal product to be assessed:	
Filgotinib additionally required SHI services Total	€ 15,046.84 € 106.40 € 15,153.24
Appropriate comparator therapy for patient population c1	
Abatacept Methotrexate additionally required SHI services Total	€ 18,930.06 € 51.98 – € 129.14 € 106.40 € 19,088.44 – € 19,165.60
Adalimumab additionally required SHI services Total	€ 11,510.06 € 106.40 € 11,616.46
Adalimumab Methotrexate additionally required SHI services Total	€ 11,510.06 € 51.98 – € 129.14 € 106.40 € 11,668.44 – € 11,745.60
Baricitinib additionally required SHI services Total	€ 14,328.26 € 106.40 € 14,434.66
Baricitinib Methotrexate additionally required SHI services Total	€ 14,328.26 € 51.98 – € 129.14 € 106.40 € 14,486.64 – € 14,563.80
Certolizumab pegol additionally required SHI services Total	€ 19,808.29 € 106.40 € 19,914.69
Certolizumab pegol Methotrexate additionally required SHI services Total	€ 19,808.29 € 51.98 – € 129.14 € 106.40 € 19,966.67 – € 20,043.83
Etanercept additionally required SHI services Total	€ 16,885.18 € 106.40 € 16,991.58
Etanercept Methotrexate	€ 16,885.18 € 51.98 – € 129.14

Designation of the therapy	Annual treatment costs per patient
additionally required SHI services Total	€ 106.40 € 17,043.56 – € 17,120.72
Golimumab Methotrexate additionally required SHI services Total	€ 20,974.88 € 51.98 – € 129.14 € 106.40 € 21,133.26 – € 21,210.42
Infliximab Methotrexate additionally required SHI services Total	€ 12,512.92 – € 25,025.83 € 51.98 – € 129.14 € 106.40 € 12,671.30 – € 25,261.37
Sarilumab	€ 17,299.30
Sarilumab Methotrexate Total	€ 17,299.30 € 51.98 – € 129.14 € 17,351.28 – € 17,428.44
Tocilizumab	€ 22,433.52
Tocilizumab Methotrexate Total	€ 22,433.52 € 51.98 – € 129.14 € 22,485.50 – € 22,562.66
Tofacitinib additionally required SHI services Total	€ 12,565.79 € 106.40 € 12,672.19
Tofacitinib Methotrexate additionally required SHI services Total	€ 12,565.79 € 51.98 – € 129.14 € 106.40 € 12,724.17 – € 12,801.33
Upadacitinib additionally required SHI services Total	€ 15,056.17 € 106.40 € 15,162.57
Upadacitinib Methotrexate additionally required SHI services Total	€ 15,056.17 € 51.98 – € 129.14 € 106.40 € 15,214.55 – € 15,291.71
Rituximab Methotrexate additionally required SHI services Total	€ 6,708.32 – € 13,416.64 € 51.98 – € 129.14 € 106.40 € 6,866.70 – € 13,652.18

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 March 2021).

c2) Adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to, or have been intolerant to previous treatment with one or more bDMARDs and/or tsDMARDs; filgotinib in combination with MTX

Designation of the therapy	Annual treatment costs per patient
Medicinal product to be assessed:	

Designation of the therapy	Annual treatment costs per patient
Filgotinib Methotrexate additionally required SHI services Total	€ 15,046.84 € 51.98 – € 129.14 € 106.40 € 15,205.22 – € 15,282.38
Appropriate comparator therapy for patient population c2	
Abatacept Methotrexate additionally required SHI services Total	€ 18,930.06 € 51.98 – € 129.14 € 106.40 € 19,088.44 – € 19,165.60
Adalimumab Methotrexate additionally required SHI services Total	€ 11,510.06 € 51.98 – € 129.14 € 106.40 € 11,668.44 – € 11,745.60
Baricitinib Methotrexate additionally required SHI services Total	€ 14,328.26 € 51.98 – € 129.14 € 106.40 € 14,486.64 – € 14,563.80
Certolizumab pegol Methotrexate additionally required SHI services Total	€ 19,808.29 € 51.98 – € 129.14 € 106.40 € 19,966.67 – € 20,043.83
Etanercept Methotrexate additionally required SHI services Total	€ 16,885.18 € 51.98 – € 129.14 € 106.40 € 17,043.56 – € 17,120.72
Golimumab Methotrexate additionally required SHI services Total	€ 20,974.88 € 51.98 – € 129.14 € 106.40 € 21,133.26 – € 21,210.42
Infliximab Methotrexate additionally required SHI services Total	€ 12,512.92 – € 25,025.83 € 51.98 – € 129.14 € 106.40 € 12,671.30 – € 25,261.37
Sarilumab Methotrexate Total	€ 17,299.30 € 51.98 – € 129.14 € 17,351.28 – € 17,428.44
Tocilizumab Methotrexate Total	€ 22,433.52 € 51.98 – € 129.14 € 22,485.50 – € 22,562.66
Tofacitinib Methotrexate additionally required SHI services Total	€ 12,565.79 € 51.98 – € 129.14 € 106.40 € 12,724.17 – €12,801.33
Upadacitinib Methotrexate additionally required SHI services Total	€ 15,056.17 € 51.98 – € 129.14 € 106.40 € 15,214.55 – € 15,291.71
Rituximab	€ 6,708.32 – € 13,416.64

Designation of the therapy	Annual treatment costs per patient
Methotrexate additionally required SHI services Total	€ 51.98 – € 129.14 € 106.40 € 6,866.70 – € 13,652.18

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 March 2021).

Other SHI services:

Designation of the therapy	Type of service	Unit cost	Number per patient per year	Costs per patient per year
Medicinal product to be assessed:				
not applicable				
Appropriate comparator therapy for patient population b				
Infliximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	6.5	€ 461.50
Appropriate comparator therapy for patient population c				
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	2 – 4	€ 142.00 – € 284.00
Infliximab			6.5	€ 461.50