Gemeinsamer Bundesausschuss

# Resolution

## of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V) Deucravacitinib (plaque psoriasis)

of 5 October 2023

At its session on 5 October 2023, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

**I. Annex XII shall be amended in alphabetical order to include the active ingredient Deucravacitinib as follows:**

**Deucravacitinib**

Resolution of: 5 October 2023
Entry into force on: 5 October 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

**Therapeutic indication (according to the marketing authorisation of 24 March 2023):**

Sotyktu is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

**Therapeutic indication of the resolution (resolution of 5 October 2023):**

See therapeutic indication according to marketing authorisation.

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

a) Adults with moderate to severe plaque psoriasis who are not candidates for a conventional therapy in the context of a first-time systemic therapy

**Appropriate comparator therapy:**

Adalimumab or bimekizumab or guselkumab or ixekizumab or secukinumab

**Extent and probability of the additional benefit of deucravacitinib compared to the appropriate comparator therapy:**

An additional benefit is not proven.

b) Adults with moderate to severe plaque psoriasis who have responded inadequately to, or have not tolerated systemic therapy

**Appropriate comparator therapy:**

Adalimumab or bimekizumab or brodalumab or guselkumab or infliximab or ixekizumab or risankizumab or secukinumab or ustekinumab

**Extent and probability of the additional benefit of deucravacitinib compared to the appropriate comparator therapy:**

An additional benefit is not proven.

**Study results according to endpoints:**[1]

a) Adults with moderate to severe plaque psoriasis who are not candidates for a conventional therapy in the context of a first-time systemic therapy

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | n.a. | There are no assessable data. |
| Morbidity | n.a. | There are no assessable data. |
| Health-related quality of life | n.a. | There are no assessable data. |
| Side effects | n.a. | There are no assessable data. |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

The presented IM011046 and IM011047 studies are unsuitable for the assessment of the additional benefit.

b) Adults with moderate to severe plaque psoriasis who have responded inadequately to, or have not tolerated systemic therapy

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
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| Mortality | n.a. | There are no assessable data. |
| Morbidity | n.a. | There are no assessable data. |
| Health-related quality of life | n.a. | There are no assessable data. |
| Side effects | n.a. | There are no assessable data. |
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The presented IM011046 and IM011047 studies are unsuitable for the assessment of the additional benefit.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-34) unless otherwise indicated.

## 2. Number of patients or demarcation of patient groups eligible for treatment

a) Adults with moderate to severe plaque psoriasis who are not candidates for a conventional therapy in the context of a first-time systemic therapy

approx. 8,100 – 8,500 patients

b) Adults with moderate to severe plaque psoriasis who have responded inadequately to, or have not tolerated systemic therapy

approx. 18,800 – 19,400 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 Sotyktu (active ingredient: deucravacitinib) at the following publicly accessible link (last access: 14 September 2023):

https://www.ema.europa.eu/en/documents/product-information/sotyktu-epar-product-information_en.pdf

## 4. Treatment costs

**Annual treatment costs:**

a) Adults with moderate to severe plaque psoriasis who are not candidates for a conventional therapy in the context of a first-time systemic therapy

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Deucravacitinib | € 13,153.69 |
| Additionally required SHI services | € 74.78 |
| Total | € 13,228.47 |
| Appropriate comparator therapy: | |
| Adalimumab | € 11,434.54 |
| Additionally required SHI services | € 181.18 |
| Total | € 11,615.72 |
| Bimekizumab | € 18,700.37 |
| Additionally required SHI services | € 74.78 |
| Total | € 18,775.15 |
| Guselkumab | € 17,110.96 |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Ixekizumab | € 16,583.41 |
| Secukinumab | € 17,858.12 |

b) Adults with moderate to severe plaque psoriasis who have responded inadequately to, or have not tolerated systemic therapy

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Deucravacitinib | € 13,153.69 |
| Additionally required SHI services | € 74.78 |
| Total | € 13,228.47 |
| Appropriate comparator therapy: | |
| Adalimumab | € 11,434.54 |
| Additionally required SHI services | € 181.18 |
| Total | € 11,615.72 |
| Bimekizumab | € 18,700.37 |
| Additionally required SHI services | € 74.78 |
| Total | € 18,775.15 |
| Brodalumab | € 17,334.05 |
| Guselkumab | € 17,110.96 |
| Infliximab | € 16,684.15 |
| Additionally required SHI services | € 181.18 |
| Total | € 16,865.33 |
| Ixekizumab | € 16,583.41 |
| Risankizumab | € 18,089.20 |
| Additionally required SHI services | € 74.78 |
| Total | € 18,163.98 |
| Secukinumab | € 17,858.12 |
| Ustekinumab | € 22,586.09 |
| Additionally required SHI services | € 74.78 |
| Total | € 22,660.87 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2023

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 | | | | |
| Infliximab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 6.5 | € 650 |

**5. Medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product**

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a) Adults with moderate to severe plaque psoriasis who are not candidates for a conventional therapy in the context of a first-time systemic therapy

No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with moderate to severe plaque psoriasis who have responded inadequately to, or have not tolerated systemic therapy

No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 5 October 2023.**

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 5 October 2023

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken