

## Format of the Pricelist of reimbursed medicinal products and foods for special medical purposes for reimbursement with order number starting from the level 4 or higher, SÚKL, version 15.0

| č. | P/N | Označení    | Тур | Velikost | Název                                      | Popis   |
|----|-----|-------------|-----|----------|--|---|
| 1  | 0   | KOD         | С   | 7        | SÚKL code                                  | The code of the medicinal product (hereinafter referred to as "MP") allocated by SÚKL to the presentation of the MP as part of the marketing authorisation (MA) of the MP.  |
| 2  | 0   | NAZ         | С   | 70       | Name of the MP                             | The name of the MP as referred to by SÚKL guideline REG-29, version 4, in compliance with Directive 2001/83/ES.   |
| 3  | 0   | DOP         | С   | 75       | Specification of the MP                    | MP name supplement, which clearly defines the presentation of the MP, comprising of an integration of its pharmaceutical form, pack size, and strength. This item of the List is further specified in the items CESTA, FORMA, BALENI and SILA.  |
| 4  | 0   | PORADI_UHRX | Ν   | 3        | Reimbursement order number                 | Reimbursement order number starting from the level 4 or higher (designated as X).   |
| 5  | 0   | UHRX        | N   | 13,2     | X-th Reimbursement                         | The amount of X-th reimbursement of the medicinal product determined by SÚKL as per Section 39d of Act No 48/1997 Coll. for the end consumer (JUHRX incremented with the maximum profit margin as per the price regulation of the Ministry of Health of the Czech Republic and VAT).  |
| 6  | 0   | JUHRX       | N   | 13,2     | X-th Core reimbursement                    | The amount of X-th reimbursement of the medicinal product determined by SÚKL as per Section 39d of Act No 48/1997 Coll or medicinal products reimbursed ex lege pursuant to Section 15 para. 4 or Sections 30 para. 2 of Act No 48/1997.  |
| 7  | 0   | LEG_JUHRX   | С   | 1        | Legal basis for X-th core<br>reimbursement | <ul> <li>The legal basis for the determination of the amount and conditions of X-th reimbursement of a MP/FSMP from health insurance; it may assume the following values:</li> <li>1 - The first temporary reimbursement of a highly innovative medicinal product as referred to by Section 39d of Act No 48/1997 Coll.;</li> <li>2 - The second temporary reimbursement of a highly innovative medicinal product as referred to by Section 39d of Act No 48/1997 Coll.;</li> <li>D - the amount and conditions of reimbursements for medicinal product included in the registry of orphan medicinal products determined pursuant to Section 39d of Act No 48/1997 Coll.;</li> <li>E - The decision on the amount and conditions of the first temporary reimbursement of a highly innovative medicinal product has not become final to date, and it is preliminarily enforceable;</li> <li>F - The decision on the amount and conditions of the second temporary reimbursement of a highly innovative medicinal product has not become final to date, and it is preliminarily enforceable;</li> <li>T - Permanent reimbursement of a highly innovative medicinal product as per Section 39d, paragraph 4 of Act No 48/1997 Coll., in the version effective until 31.12.2021;</li> <li>V - The MP is reimbursed ex lege within reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll., as amended in the least economically demanding presentation;</li> <li>W – The MP is reimbursed ex lege within the reimbursed care under Section 30 para. 2 of Act No. 48/1997 Coll. It concerns medicinal products containing vaccines that are approved by the Ministry of Health based on the recommendation of the National Immunization Commission and published in the form of a notice in the Collection of Laws;</li> <li>Y - The decision on the amount and conditions of permanent reimbursement of a highly innovative medicinal product under Section 39d, paragraph 4 of Act No 48/1997 Coll., has not become final to date, and it is preliminarily enforceable;</li> </ul> |



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| 8  | 0   | ODKAZ_JUHRX        | С   | 20       | Grounds for X-th core<br>reimbursement amount<br>determination | Contains the file no. of SÚKL administrative procedure.,   |
| 9  | 0   | LIMX               | С   | 2        | X-th reimbursement reporting limit                             | The method of reporting MPs/FSMPs to the health insurance company.<br>A common LIM status value implemental index is available for the LIMX fields.  |
| 10 | 0   | OMEX               | С   | 40       | Prescribing doctor's specialisation                            | The specification of prescription restriction for X-th MP/FSMP reimbursement based on the specialization of the prescribing doctor. For a single MP/FSMP code it may assume several OMEX values.<br>A common OME status value implemental index is available for the OMEX fields.  |
| 11 | 0   | INDX               | С   | 1        | Indication restriction flag                                    | Indication restriction (P) for the X-th reimbursement of an MP/FSMP. The DETINDX implemental index is available for the indication restriction detail (indication or clinical condition conditioning X-th reimbursement of the MP/FSMP).<br>In respect of medicinal products reimbursed <i>ex lege</i> pursuant to Section 30 of Act No 48/1997 Coll., as amended, the particular provision of the Act is cited.   |
| 12 | 0   | PUHRX              | С   | 1        | Full reimbursement flag  | <ul> <li>The full reimbursement flag may assume the following values:         <ul> <li>I - the least economically demanding presentation of MPs fully reimbursed under the law;</li> <li>J - MPs where MFC &lt;= UHRX. Note: Final sales under the pricing regulations of the Ministry of Health of the Czech Republic are disregarded. Where final sales for a higher price in compliance with a price regulation of the Ministry of Health of the Czech Republic is applied, the applied price for the end consumer may exceed the specified amount of reimbursement;</li> <li>M – MP containing vaccines approved by the Ministry of Health pursuant to Section 30 par. 2 of Act No. 48/1997 Coll. (Reimbursement determined ex lege is equal to MFC.);</li> <li>U – MPs fully reimbursed under reimbursement agreements referred to under Section 39c, paragraph 2(d) of Act No 48/1997 Coll.</li> </ul> </li> </ul> |
| 13 | 0   | JUHRX_PLATDO       | D   | 8        | Temporary reimbursement expiry date                            | The temporary reimbursement is determined for the period of 24 or 12 months pursuant to Section 39d, paragraph 4 of Act No 48/1997 Coll., in the version effective until 31.12.2021 or for the period of 36 or 24 months pursuant to Section 39d, paragraph 4 of Act No 48/1997 Coll., in the version effective from 31.12.2021. The field is populated with the expiry date of the temporary reimbursement.   |
| 14 | 0   | ODTDX              | N   | 13,4     | Usual daily therapeutic dose for X-th reimbursement            | The usual daily therapeutic dose for X-th reimbursement  |
| 15 | 0   | ODTDJX             | С   | 5        | Unit of active substance<br>amount in ODTDX                    | The usual daily therapeutic dose for reimbursement unit for ODTDX  |
| 16 | 0   | ODTDBALX           | N   | 11,4     | Number of ODTDX in a MP pack                                   | The number of usual therapeutic doses in a pack for ODTDX.   |
| 17 | 0   | ZU_ODTDX           | N   | 13,4     | Reimbursement for ODTDX  | X-th reimbursement of a MP for ODTDX, determined by SÚKL as per Section 39d of Act No 48/1997 Coll.  |
| 18 | 0   | ODKAZ_ZU_ODT<br>DX | С   | 20       | Grounds for EKVX<br>determination                              | Contains the file no. of SÚKL administrative procedure.  |



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| 19 | 0   | ZAPX     | Ν   | 13,2     | 8                        | An eligible extra payment for UHRX under a communication of the Ministry of Health of the Czech Republic,  |
|    |     |          |     |          | extra                    | stipulated in compliance with Section 16b, paragraph 1 of Act No 48/1997 Coll.   |
|    |     |          |     |          | payment                  |  |
| 20 | 0   | NEZAPX   | С   | 1        | Limit eligibility symbol | A flag of the category of the pharmaceutical (eligibility for the limit) under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, paragraph 1 of Act No 48/1997 Coll. The <b>NEZAP</b> implemental index is available for the NEZAPX field. |

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CZ Field separator "I"

The "M/O" column identifies mandatory and optional fields in the List

The "Type" column identifies the format of the fields as follows:

"C" character attribute

"N" numeric attribute

"D" date in the "ddmmyyyy" format

The "Size" column identifies the scope of the fields. The format of numeric fields is identified as "x,y" ("x" positions, incl. the decimal point, of which "y" are decimals