

Format of the Pricelist of reimbursed foods for special medical purposes, SÚKL, version 01

| No. | M/O | Label | Туре | Size | Name | Description |
|-----|-----|-------------|------|------|---|--|
| 1 | М | KOD | С | 7 | SÚKL code | The code of food for special medical purposes (hereinafter referred to as "FSMP") allocated by State Institute for Drug Control (hereinafter referred to as "SÚKL") to the presentation of the FSMP as part of an application for the determination of the maximum price and the amounts and conditions of reimbursement or as part of the notification of categorized FSMP for their inclusion in reimbursement groups. |
| 2 | М | NAZ | С | 70 | Name of the FSMP | The name of the FSMP |
| 3 | М | CESTA | С | 15 | Route of administration | Route of administration |
| 4 | М | DOP | С | 75 | Specification of the FSMP | FSMP name supplement, comprising of an integration of its pharmaceutical form and strength. |
| 5 | М | OBAL | С | 3 | Packaging | Abbreviation for FSMP packaging |
| 6 | М | DOV_VYR | С | 3 | Importer or domestic manufacturer | The abbreviation of the importer or domestic manufacturer stated on the FSMP packaging label. A common implemental index is available for the DOV_VYR and ZEMDOV_VYR fields. |
| 7 | М | ZEMDOV_VYR | С | 3 | Importer's or domestic manufacturer's country | The abbreviation of the country of the manufacturer's or importer's registered office. A common implemental index is available for the DOV_VYR and ZEMDOV_VYR fields. |
| 8 | М | TCR | С | 3 | Price regulation type | The of price regulation applicable values: MCV – Maximum ex-factory price determined by SÚKL for uncategorized FSMP or pursuant to Part Six of Act No. 48/1997 Coll., on public health insurance, as amended (hereinafter also referred to as "Act No. 48/1997 Coll.") effective until December 31, 2025. VUC – regulation through substantive price regulation of categorized FSMP. The maximum possible year-on-year price increase is set by the Ministry of Health in a price assessment. |
| 9 | М | CV | N | 13,2 | Ex-factory price | Ex-factory price of the FSMP, depending on the TCR field, is the maximum ex-factory price or the announced ex-factory price or the contractual price. |
| 10 | М | CV_REF_JEDN | N | 13,2 | Ex-factory price converted to reference unit | Ex-factory price converted to reference unit. |
| 11 | 0 | LEG_CV | С | 10 | Ex-factory price legal basis | The legal basis for the determination of the producer price of a FSMP; it may assume the following values: N – maximum ex-factory price stated in the application, for which the applicant may place the FSMP on the market if their application has not been decided within timelines set forth by Act No. 48/1997 Coll., as amended. This price equals the price specified in the application for maximum price determination or reimbursement. The validity of this price is limited until an enforceable decision is issued on the matter. O – announced ex-factory price S – maximum ex-factory price was determined or amended via an administrative procedure for uncategorized FSMP or for FSMP in accordance with Part Six of Act No. 48/1997 Coll. as amended, effective until December 31, 2025. Q – contract/agreed price pursuant to Section 39zf of Act No. 48/1997 Coll. X – The decision on the maximum ex-factoy price determined or amended via an administrative procedure for uncategorized FSMP has not become final to date, and it is preliminarily enforceable. |
| 12 | 0 | ODKAZ_CV | С | 20 | Grounds for CV determination | If the TCR field contains the "MCV" value, this field will contain the file no. of SÚKL administrative procedure. If the TCR field contains the "VUC" value, this field will contain the file no. of the notification. |

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|-----|-----|-------------|------|------|---|---|
| 13 | M | UHR1 | N | 13,2 | Reimbursement | The amount of reimbursement of the categorized FSMP for the end consumer (JUHR1 incremented with the maximum profit margin as per the price regulation of the Ministry of Health of the Czech Republic and VAT). The amount of reimbursement of the uncategorized FSMP for the end consumer is set at 70% of the final price for end consumer (MFC) or at a higher amount in the public interest pursuant to Section 17 para. 2 of Act No. 48/1997 Coll. The amount of reimbursement for the end consumer determined in accordance with Part Six of Act No. 48/1997 Coll. as amended, effective until December 31, 2025. (JUHR1 incremented with the maximum profit margin as per the price regulation of the Ministry of Health of the Czech Republic and VAT). |
| 14 | 0 | JUHR1 | N | 13,2 | Core reimbursement | The amount of the core reimbursement for categorized FSMP packaging is based on the basic reimbursement of the relevant reimbursement group converted to the size of the packaging (number of reference units per FSMP pack). The amount of the core reimbursement for FSMP packaging determined by the SÚKL pursuant to Section 39g, para. 4 of Act No. 48/1997 Coll. as amended, effective until December 31, 2025, or calculated from the UHR1 determined for uncategorized FSMP pursuant to Part Eight of Act No. 48/1997 Coll. |
| 15 | 0 | LEG_JUHR1 | С | 1 | Legal basis for core reimbursement | The legal basis for the determination of the amount and conditions of core reimbursement of a FSMP from health insurance; it may assume the following values: S - Established or amended via administrative proceedings for uncategorized FSMP or for FSMP pursuant to Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. X - The decision on the amount and conditions of reimbursement for uncategorized FSMP has not become final to date, and it is preliminarily enforceable. K - categorized FSMP |
| 16 | 0 | ODKAZ_JUHR1 | С | 20 | Grounds for core reimbursement amount determination | Contains the file no. of SÚKL administrative procedure pursuant to Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025, or pursuant to Part Eight in the case of uncategorized FSMP, or the file no. of a measure of a general nature or the notification of categorized FSMP. |
| 17 | M | LIM1 | С | 2 | Reporting limit | The method of reporting FSMPs to the health insurance company. A common LIM_PZLÚ status value implemental index is available for the LIM1, LIM2 fields. For categorized FSMP reimbursed as partial or complete enteral nutrition, this is the method of reporting for reimbursement as partial enteral nutrition. |
| 18 | M | OME1 | С | 40 | Prescribing doctor's specialization | The specification of prescription restriction based on the specialisation of the prescribing doctor. For a single FSMP code it may assume several OME1 values. A common OME_PZLÚ status value implemental index is available for the OME1 and OME2 fields. For categorized FSMP reimbursed as partial or complete enteral nutrition, this is a specification of the prescribing doctor for reimbursement as partial enteral nutrition. |
| 19 | M | IND1 | С | 1 | Indication restriction flag | Indication restriction (P). For the indication restriction detail (according to Annex No. 6 to Act No. 48/1997 Coll) or if specified by a decision of the SÚKL on uncategorized FSMP, which is a condition for the reimbursement of FSMP, the DETIND1_PZLÚ implemental index is available. For categorized FSMP reimbursed as partial or complete enteral nutrition, this is an indication restriction for reimbursement as partial enteral nutrition. |
| 20 | 0 | PUHR1 | С | 1 | Full reimbursement flag | The full reimbursement flag may assume the following values: J - FSMPs where MFC <= UHR1. 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. |

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|-----|-----|--------------|------|------|--|---|
| 21 | 0 | ZU_US_PLATDO | D | 8 | Validity of the basic reimbursement of the reimbursement group | Validity of the time-limited basic reimbursement for the FSMP reimbursement group set by a measure of a general nature pursuant to Section 39zf(6) of Act No. 48/1997 Coll. |
| 22 | М | MNZ_OMZ1 | N | 70 | Quantity restrictions partial enteral nutrition | Quantity restrictions (max. limit kcal/day) for partial enteral nutrition according to Table No. 2 and for enteral nutrition according to Table No. 1 of Annex No. 6 to Act No. 48/1997 Coll. or determined by a decision of the SÚKL on uncategorized FSMP. For categorized FSMP reimbursed as partial or complete enteral nutrition, this is a quantitative restriction on reimbursement as partial enteral nutrition. |
| 23 | 0 | DNC | С | 1 | Written arrangement on price in public interest | Identification of the maximum price (X) agreed between the health insurance company and the importer or domestic manufacturer of FSMP. If the calculated MFC is lower than the agreed maximum price announced by the health insurance company, the field will contain the "Y" value. |
| 24 | М | UHR2 | N | 13,2 | Second reimbursement | The amount of the second reimbursement for the end consumer of a FSMP determined in accordance with Part Six of Act No. 48/1997 Coll. as amended, effective until December 31, 2025. (JUHR2 incremented by the maximum profit margin as per the price regulation of the Ministry of Health of the Czech Republic and VAT). |
| 25 | 0 | JUHR2 | N | 13,2 | Second core reimbursement | The amount of the second core reimbursement of a FSMP determined by SÚKL pursuant to Section 39b, para. 4, of Act No. 48/1997 Coll as amended, effective until December 31, 2025. |
| 26 | 0 | LEG_JUHR2 | С | 1 | Legal basis for second core reimbursement | The legal basis for the determination of the amount and conditions of core reimbursement of a FSMP from health insurance; it may assume the following values: Z – Other increased reimbursement determined as per Section 39b, para. 11 of Act No. 48/1997 Coll, pursuant to Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 27 | 0 | ODKAZ_JUHR2 | С | 20 | Grounds for second reimbursement determination | Contains the file no. of SÚKL administrative procedure pursuant to Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 28 | M | LIM2 | С | 2 | Second reimbursement reporting limit | The method of reporting second reimbursement of FSMP with the determined second reimbursement pursuant to Section 39b, Para. 11 of Act No. 48/1997 Coll. according to Part Six of Act No. 48/1997 Coll. as amended, effective until December 31, 2025, to the health insurance company. A common LIM_PZLÚ status value implemental index is available for the LIM1, LIM2 fields. For categorized FSMP reimbursed as partial or complete enteral nutrition, this is the method of reporting for reimbursement as complete enteral nutrition. |
| 29 | М | OME2 | С | 40 | Prescribing doctor's specialisation | Specification of prescription restriction for the second FSMP reimbursement based on the specialisation of the prescribing doctor. For a single FSMP code it may assume several OME2 values. A common OME_PZLÚ status value implemental index is available for the OME1 and OME2 fields. For categorized FSMP reimbursed as partial or complete enteral nutrition, this is a specification of the prescribing doctor for reimbursement as partial enteral nutrition. |
| 30 | М | IND2 | С | 1 | Indication restriction flag | Indication restriction (P) for the second reimbursement of an FSMP. The DETIND2_PZLÚ implemental index is available for the indication restriction detail (indication or clinical condition conditioning the second reimbursement of the FSMP). For categorized FSMP reimbursed as partial or complete enteral nutrition, this is an indication restriction for reimbursement as partial enteral nutrition. |
| 31 | 0 | PUHR2 | С | 1 | Full reimbursement flag | The full reimbursement flag may assume the following values: J - for FSMPs which are fully reimbursed in case MFC <= UHR2. 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. |

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|-----|-----|--------------|------|------|--|---|
| 32 | М | MNZ_OMZ2 | N | 70 | Quantity restrictions total enteral nutrition | Quantity restrictions (maximum limit of kcal/day) for complete enteral nutrition according to Table No. 2 of Annex No. 6 to Act No. 48/1997 Coll. or specified by a decision of the SÚKL on uncategorized FSMP. For categorized FSMP reimbursed as partial or complete enteral nutrition, it is a quantitative restriction in reimbursement as complete enteral nutrition. |
| 33 | М | US | N | 4 | Designation of the reimbursement group | K poli UH_SK_OZN je k dispozici pomocný číselník s názvy úhradových skupin kategorizovaných PZLÚ. Designation of reimbursement groups for categorized FSMP according to Annex No. 6. The implemental index with the names of reimbursement groups of categorized FSMP is available for the UH_SK_OZN field. |
| 34 | 0 | RS | С | 6 | Reference group | The applicable reference group of the FSMP where the FSMP has been allocated a reference group when establishing the amount and conditions of reimbursement; it shall comprise of the applicable therapeutic group (TS), separator (/), sequence of the subgroup of products that are similar or that can cause confusion in the reference group (RS_P); the RS stipulated by a decree of the Ministry of Health of the Czech Republic under authority referred to under Section 39c, para. 1 of Act No. 48/1997 Coll. as amended, effective until December 31, 2025. |
| 35 | 0 | TS | N | 3 | Therapeutic group | The applicable therapeutic group of the FSMP if it has been allocated a therapeutic group when establishing the amount and conditions of reimbursement of FSMP; the TS stipulated by a decree of the Ministry of Health of the Czech Republic under authority referred to under Section 39c, para. 1 of Act No. 48/1997 Coll, as amended, effective until December 31, 2025. |
| 36 | 0 | TS_P | N | 2 | TS subgroup | The applicable subgroup of products that are similar or that can cause confusion within the TS of the FSMP where an RS has been allocated when establishing the amount and conditions of reimbursement; the TS_P stipulated by a decree of the Ministry of Health of the Czech Republic under authority referred to under Section 39c, para. 1 of Act No. 48/1997 Coll, as amended, effective until December 31, 2025. |
| 37 | 0 | HL_UV_OD | D | 8 | Placement on the market | Date of initial placement of supplies of the FSMP on the market or reinstitution thereof, by the importer / domestic manufacturer in pursuant to Section 39zi of Act No. 48/1997 Coll. |
| 38 | 0 | HL_UK_DO | D | 8 | Supply termination | Date of termination or discontinuation of supplies of the FSMP onto the market, to be reported by the importer/domestic manufacturer in pursuant to Section 39zi of Act No. 48/1997 Coll. |
| 39 | М | ENERG_HODN | N | 70 | Energy value | Energy value (kcal) of the FSMP indicated on the product packaging label. |
| 40 | М | EV | С | 10 | Partial or total enteral nutrition identifier | The indicator of fulfillment of the condition for categorized foods for reimbursement as partial or complete enteral nutrition acquires values: C – FSMP is reimbursed as partial enteral nutrition U – FSMP is reimbursed as total enteral nutrition CU – FSMP is reimbursed as both partial and total enteral nutrition |
| 41 | М | REF_JEDN | С | 20 | Reference unit | Reference unit of the relevant reimbursement group FSMP. |
| 42 | М | REF_JEDN_BAL | N | 11,4 | Number of REF_JEDN1 per pack | Number of Reference units per FSMP pack. |
| 43 | 0 | ODTD1 | N | 13,4 | Usual daily therapeutic dose for reimbursement | The usual daily therapeutic dose for reimbursement determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 44 | 0 | ODTDJ1 | С | 10 | Unit of active substance amount in ODTD1 | The usual daily therapeutic dose for reimbursement unit for ODTD1 determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |

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|-----|-----|----------------|------|------|--|--|
| 45 | 0 | ODTDBAL1 | N | 11,4 | Number of ODTD1 in a FSMP pack | The number of usual therapeutic doses in a pack for ODTD1 determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 46 | 0 | ODTD2 | N | 13,4 | Usual daily therapeutic dose for second reimbursement | The usual daily therapeutic dose for second reimbursement determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 47 | 0 | ODTDJ2 | С | 10 | Unit of active substance amount in ODTD2 | The usual daily therapeutic dose for second reimbursement unit for ODTD2 determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 48 | 0 | ODTDBAL2 | N | 11,4 | Number of ODTD2 in a FSMP pack | The number of usual therapeutic doses in a pack for ODTD2 determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 49 | М | ZU_UH_SK | N | 13,4 | Reimbursement for ODTD of the reimbursement group | Reimbursement for ODTD of the reimbursement group of categorized FSMP. |
| 50 | 0 | ZU_ODTD1 | N | 13,4 | Reimbursement for ODTD1 | Basic reimbursement of the active substance or reference group for FSMP, if it has been determined by SÚKL pursuant to Section 39c, para. 1 and para. 2 resp. to Section 39d of Act No. 48/1997 Coll, as amended, effective until December 31, 2025. |
| 51 | 0 | ODKAZ_ZU_ODTD1 | С | 20 | Grounds for ZU_ODTD1 determination | Contains the file no. of SÚKL administrative procedure determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 52 | 0 | ZU_ODTD2 | N | 13,4 | Reimbursement for ODTD2 | The second reimbursement of the active substance or pseudo-reference group for FSMP, if it has been determined by SÚKL pursuant to Section 39b, para. 11 resp. to Section 39d of Act No. 48/1997 Coll, as amended, effective until December 31, 2025. |
| 53 | 0 | ODKAZ_ZU_ODTD2 | С | 20 | Grounds for ZU_ODTD2 determination | Contains the file no. of SÚKL administrative procedure determined in accordance with Part Six of Act No. 48/1997 Coll., as amended, effective until December 31, 2025. |
| 54 | 0 | DAT_CV | D | 8 | CV validity | The effective date of an ex-factory price change. |
| 55 | 0 | DAT_UHR | D | 8 | UHR validity | The date of change of the determination of the amount and conditions of reimbursement. |
| 56 | 0 | ZAP1 | N | 13,2 | Eligible extra payment | An eligible extra payment for UHR1 under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, para. 1 of Act No. 48/1997 Coll. |
| 57 | 0 | NEZAP1 | С | 1 | Limit eligibility symbol | A flag of the category of the FSMP (eligibility for the limit) under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, para. 1 of Act No. 48/1997 Coll. The NEZAP implemental index is available for the NEZAP1 field. |
| 58 | 0 | ZAKL_ZAP1 | С | 1 | Eligible extra payment calculation base | Contains the "X" value only for FSMP s that form the basis for the calculation of the eligible extra payment under Section 16b, para. 1 of Act No. 48/1997 Coll. |
| 59 | 0 | ZAP2 | N | 13,2 | Eligible extra payment for second reimbursement | An eligible extra payment for UHR2 under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, para. 1 of Act No. 48/1997 Coll. |
| 60 | 0 | NEZAP2 | С | 1 | Limit eligibility symbol | A flag of the category of the FSMP (eligibility for the limit) under a communication of the Ministry of Health of the Czech Republic, stipulated in compliance with Section 16b, para. 1 of Act No. 48/1997 Coll. The NEZAP implemental index is available for the NEZAP2 field. |
| 61 | 0 | ZAKL_ZAP2 | С | 1 | Eligible extra payment calculation base for second reimbursement | Contains the "X" value only for FSMP s that form the basis for the calculation of the eligible extra payment under Section 16b, para. 1 of Act No. 48/1997 Coll. |

| No. | M/O | Label | Туре | Size | Name | Description |
|-----|-----|--------|------|------|---------------------------------|--|
| 62 | 0 | MFC | N | 13,2 | Final price | Final price – the price for the end consumer (producer price plus the maximum profit margin under the price regulation of the Ministry of Health and VAT). If the insurance company and the MA holder concluded an agreement on the maximum agreed price for the product or assumed a valid obligation not to exceed the price assumed in a pricing tender under Section 39 of Act No. 48/1997 Coll., as amended prior to the technical amendment, the agreed price, lower than the MFC, will be specified in this field. If the calculated MFC is lower than the agreed maximum price announced by the insurance company or the price assumed in the pricing tender, the calculated MFC value will be specified in this field. |
| 63 | 0 | DPH | N | 13,0 | Value-added tax rate | Contains a numerically expressed value-added tax rate. |
| 64 | 0 | PAR_SK | С | 8 | Identification code of parallel | Identifier of a parallel group of identical FSMP in compliance with Section 39b para. 9 of Act No. 48/1997 |
| 65 | 0 | ATC | С | 7 | ATC | Anatomical therapeutic chemical group. |

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Field separator "|"
The "M/O" column identifies mandatory and optional fields in the List
The "Type" column identifies the format of the fielts 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 decimal)