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| Název: Procedure for determination of the maximum price and the amount and terms of reimbursement of a similar product – summary procedure | | |

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| Document owner: Name: Mgr. Kateřina Podrazilová, Ph.D. 33020 | Reviewed by MJ: Name: ing. Radmila Foretová | Approved by: Name: MUDr. Mgr. Jindřich Kotrba 33000 |
| Department Date Signature | Date Signature | Department Date Signature |

1. OBJECTIVE

Establish the procedure for determination of the maximum price and the amount and terms of reimbursement of a similar product.

Analogical procedure shall be applied also for the determination of the maximum price under Section 39i (4) of the Public Health Insurance Act z.

2. USERS

The procedure is binding on the employees of the Price and Payment Regulation Section.

3. DEFINITION OF TERMS AND ABBREVIATIONS

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| ADM | Administrative employee |
| DTB | Database employee |
| CAU | Price and reimbursement regulation |
| EV | Evaluator |
| LF | Coming into force |
| LD | Legal Department |
| FSMP | Food for special medical purposes |
| SA | Department of statistics and analyses |
| APMPD | Administrative procedure – Medicinal Products Database |
| AAFS | AthenA filing service |
| UR | Department for determination of the amount and terms of reimbursement |
| VAL | Validation Department |
| APHI | Act No. 48/1997 Coll., on Public Health Insurance and amendments to some related acts, as amended |

ADM – an employee responsible for formal correctness of the administrative procedure, use of up-to-date data (participants in the procedure, product codes, etc.) and up-to-date forms, completion of assigned tasks – a task is considered to have been completed upon change of phase in APMPD and the check of the change on the following day. He/she follows the instructions of the Coordinator and Evaluator. He/she is authorized to complete simple forms and prepares them to be signed.

Evaluator (specialist) – an employee responsible for completeness, correctness and expert processing of all materials necessary for a smooth course of the AP assigned to him/her, including the Evaluation Report and the Decision.

Within the evaluation, the Evaluator either prepares materials for the determination of reimbursement or asks the employee responsible for the preparation of pricing documentation to submit such materials.

If the procedure does not require the assistance of a Coordinator, the Evaluator is also responsible for the management of the procedure, which he/she carries out with the support of the administrative employees.

The Evaluator responsible for the given procedure prepares the documents necessary for determination of the maximum price or the amount of reimbursement or assigns the preparation of the documentation to another employee.

Official - any person who takes part in the course of the procedure or preparation of documents relevant to any decision taken within the procedure. The name of the person responsible for each act within the administrative procedure is always stated under the performed act or in association with the act in the AA FS

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and APMPD application. The person leading the administrative procedure is stated in the AA FS and APMPD as the file owner.

Authorized Official – a person performing acts in the competence of an administrative authority authorized to do so by the internal regulations of the administrative authority or appointed by the head of the administrative authority. The authorized official in the procedures relevant to prices and reimbursements is the head of the department or other superior head according to S-001 Approval Rule.

4. RELATED INTERNAL REGULATIONS

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| SP-UST-013 | Appeal against a decision issued by the State Institute for Drug Control |
| F-105 | Internal Review |
| SP-CAU-023 | Procedure for the creation of the list of reimbursed HVLP FSMP |
| S-001 | Approval Rule |
| S-005 | File processing and shredding rules |
| PN-CAU-001 | CAU reference registry |

5. RELATED GENERALLY APPLICABLE LEGAL REGULATIONS, NORMS AND EU REGULATIONS

Act No. 500/2004 Coll., Rules of Administrative Procedure, as amended (“Administrative Code”)

Act No. 48/1997 Coll., on Public Health Insurance and amendments to some related acts, as amended

Act No. 634/2004 Coll., on administrative fees, as amended (“Administrative Fees Act”)

Regulation No. 92/2008 Coll., on the creation of the list of reference countries, the manner of evaluation of the amount, terms and form of reimbursement of medicinal products and foods for special medical purposes and the elements of the application, as amended

Act No. 261/2007 Coll., on stabilization of public budgets, part forty-eight, amending Act No. 265/1991 on the competence of Czech authorities concerning prices 265/1991

Act No. 265/1991 Coll., on the competence of Czech authorities concerning prices, as amended

Act No. 526/1990 Coll., on prices, as amended

Act No. 362/2009 Coll., amending some acts related to the proposal of the Act on the State Budget of the Czech Republic for 2010

Price Decision of the Health Ministry of 20.12.2007, setting the terms of price regulation of medicinal products and foods for specific medical purposes

Price Decision of the Health Ministry 1/2010-FAR, which stipulates the list of ATC groups of medicinal products and foods for special medical purposes – regulation of ex-factory price as amended

Health Ministry Price Regulation 2/2009/FAR of 20 March 2009 on the regulation of price of medicinal products and foods for special medical purposes, as amended

6. PROCEDURE

The procedure for the implementation of a reimbursement tender is described in the table and the development diagram – Annex 1.

| Activity | Description | Performed by | Document/ tool/ system |
|---------------------------|---|-------------------------|------------------------|
| 1. Acceptance of the file | The UR secretariat receives the file from the VAL in an electronic form through the APMPD, or in a paper form if necessary (within 24 hours). | ADM CAU VAL employee | APMPD AA FS |
| 2. Assignment of the | The UR/SA head assigns the file to the | UR/SA Head | APMPD |

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| file | Evaluator. The UR/SA secretariat forwards the file to the EVA through the AA FS. The file is also forwarded via the APMPD application. The paper version of a file for an EVA from Brno is kept by the appointed ADM employee. | ADM CaU | AA FS |
| 3. Setup of file sharing | The Evaluator sets up the rights to handle the file in the APMPD for the ADM and other employees where applicable. | EVA | AA FS |
| 4. Data check | The EVA checks whether the filed documentation includes the necessary information on the similar product according to Section 39g (9) of the APHI. Where the first similar product is concerned, the EVA checks whether the merchandisability declaration has been enclosed (under Section 15(6)(e) of the APHI). Identical procedure is applied to a reduction of the maximum price in accordance with Section 39i(4) of the APHI, except for the assessment of similarity of the product. | EVA | APMPD AA FS |
| 5. Steps to be taken upon commencement of the procedure | (Within 48 hours following the filing of the application.) According to the instruction of the EVA, the ADM fills in the forms “Notice of commencement of a summary procedure for similar products” and “Notice of termination of gathering of documentation” in the APMPD application and determines the time limit for providing of an opinion on the documentation relevant to the decision (5 days). The EVA also reduces the time limit for submitting of evidence and other motions under Section 36 (1) of the Rules of Administrative Procedure. The ADM forwards the document via APMPD to the UR/SA Head for signature. The UR/SA Head checks the document, | ADM UR/SA Head | APMPD AA FS |

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| | <p>signs it and incorporates in the file or returns it for amendments.</p> <p>ADM incorporates the document in the file and ensures its posting on the official notice board via the APMPD.</p> <p>The ADM employee enters the date of publication of the resolution in the APMPD.</p> <p>Other options are indicated under step 6.</p> | | |
| 6. A. Incomplete application | <p>If the application does not contain the necessary elements, the ADM prepares, according to the instructions of the EVA, a call to add the missing information under Section 45(2) of the Rules of Administrative Procedure and a resolution on the suspension of the administrative procedure according to Section 64 (1)(a) of the Rules of Administrative Procedure. The EVA checks the call and resolution on suspension and hands them over to the department Head for signature. If the missing elements are not supplied within the stipulated time limit, the EVA, upon expiration of the time limit, discontinues the procedure by a resolution issued according to Section 66(1)(c) of the Rules of Administrative Procedure. If the missing elements have been supplied, the procedures continues from step 7 D.</p> | Evaluator ADM | APMPD AA FS |
| 6 B. The application is complete but the conditions according to Section 39g(9) have not been met and at least one participant gives its consent to this procedure and files an objection against the procedure according to | <p>The ADM prepares for the EVA a Notice of termination of gathering of documentation and the resolution on the stipulation of a 5-day period for issuance of a position on the documentation relevant to the decision, by which the application is dismissed. If, in the time limit stipulated in the first sentence:</p> <p>a) The applicant subsequently fulfils the condition under Section 39g(9) in the stipulated time limit, but the other participants have consented to the discontinuance of the AP,</p> | EVA/ADM | APMPD AA FS |

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| Section 39(9) | <p>then the EVA issues an affirmative decision within the respective time limit.</p> <p>b) The applicant subsequently fulfils the conditions under Section 39g(9) in the stipulated time limit and the other participants have not consented to the discontinuance of the AP, in which case the EVA issues the decision</p> <p>c) The applicant fails to subsequently fulfil the conditions under Section 39g(9) in the stipulated time limit and at least one participant consents to discontinuance, in which case the EVA issues a decision on discontinuance of the administrative procedure under Section 66(1)(h) of the Rules of Administrative Procedure in combination with Section 39g(10) of the APHI</p> <p>d) The applicant fails to subsequently fulfil the conditions under Section 39g(9) in the stipulated time limit, and the consent to discontinue the procedure is not given in time, in which case the EVA issues a decision on dismissal of the application under Section 51(3) of the Rules of Administrative Procedure.</p> | | |
| 6 C. The application is complete but the conditions under Section 39g (9) have not been fulfilled and none of the participants has expressed its consent to | <p>The ADM prepares for the EVA the Notice of termination of gathering of documentation and the resolution stipulating the time limit of 5 days for providing of an opinion on the documentation relevant to the decision, by which the application is dismissed. If, within the time limit stipulated in the first sentence:</p> <p>a) The applicant fails to</p> | ADM/EVA | APMPD AA FS |

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| discontinue the AP | <p>subsequently fulfil the conditions under Section 39g(9) in the stipulated time limit, the EVA issues a resolution on the dismissal of the application according to Section 51(3) of the Rules of Administrative Procedure.</p> <p>b) The applicant subsequently fulfils the condition under Section 39g (9) in the stipulated time limit, the EVA issues he second Notice of termination of gathering of documentation and subsequently issues a decision in the respective time limit, or, if the time limit for issuance lapses, the fiction of a decision is applied.</p> | | |
| 6 D. The application is complete and meets the conditions under Section 39c(9) | <p>The ADM prepares for the EVA the Notice of termination of gathering of documentation and the resolution stipulating the time limit of 5 days for providing of an opinion on the documentation relevant to the decision, by which the application is satisfied. In the time limit according the first sentence:</p> <p>a) At least one of the participants expresses its disapproval of this procedure, in which case the EVA evaluates once more whether the conditions under Section 39 f (8) have been fulfilled:</p> <ol style="list-style-type: none"> 1) If it is ascertained that the conditions have been met and at the same time a consent is given to discontinue the AP, then an affirmative decision is issued in the respective time limit. 2) If it is ascertained that the conditions have been met and the consent to discontinue the AP has not been given, an affirmative decision is issued in the respective time limit 3) If it is ascertained that the conditions have not been met and the consent to discontinue the AP has been | ADM/EVA | APMPD AA FS |

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| | <p>given, a resolution on discontinuance of the AP is issued under Section 39g(10)</p> <p>4) – if it is ascertained that the conditions have not been met and the consent to discontinue the AP has not been given, the AP is dismissed under Section 51 (3) of the Rules of Administrative Procedure</p> <p>b) None of the participants disapproves of this procedure, in which case the EVA issues a decision in the respective time limit, or, if the time limit for issuance lapses, the fiction of a decision is applied.</p> | | |
| 7. Revision of the decision | <p>If the conditions for the issuance of a decision have been fulfilled, the Evaluator fills in the decision form and the Decision is subsequently checked by the UR/SA Head. If the time for its issuance lapses, the procedure continues according to step 12 and the following.</p> <p>A Decision is always issued in the cases when the application is dismissed.</p> | Coordinator UR/SA Head | |
| 8. Signing of the Decision | <p>The UR/SA Head checks the Decision and signs it or returns it to the Evaluator for amendments. The ADM incorporates the signed decision in the file.</p> | CAU Head ADM | APMPD |
| 9. Sending of the decision to the participants in the procedure | <p>The ADM ensures the publishing of the Decision on the Institute's official notice board via the AA FS.</p> | ADM | AA FS |
| 10. Handover of the file and indication of legal force | <p>The EVA hands the Decision over to the DTB employee, who indicates the date of legal force in it and incorporates the Decision including the legal force clause in the file, unless an appeal has been filed in the respective time limit.</p> | EVA DTB employee | SP-UST-013 |
| 11. Setup of reimbursements in the MPD, enforceability. | <p>In the case of a fictitious decision the Evaluator calculates the price and reimbursement immediately after the lapse of the time limit for issuance of an opinion on the documentation.</p> <p>The EVA forwards the information on the decision to the DTB employees, who</p> | EVA, DTB employee | e-mail |

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| | <p>process it (enter the data in the information system) for the purpose of creation of the List of Reimbursed MP/FSMP.</p> <p>The decision is (preliminarily) enforceable as of the first day of the following month upon the lapse of the time limit for filing of an appeal on the 14th day of the preceding month.</p> | | |
| 12. Appeal delivery monitoring | <p>An appeal against the decision does not have a suspensory effect.</p> <p>Monitoring of the delivery of an appeal against the Decision (which is handed over from the filing office to the legal department, the LD forwards the information via e-mail and enters the data in the appeal table in the share Public folder). If the appeal has been delivered in time and contains all the required elements, (to be confirmed by the LD), the procedure continues with step 15.</p> <p>If the appeal has not been delivered in the respective time limit, the procedure continues under the management of the LD.</p> | EVA Filing office LD Head and employees ADM support of the UR | APMPD e-mail |
| 13. Preparing a Position on the appeal | <p>The EVA prepares a Position on the appeal and hands it over to the UR/SA Head or prepares a proposal for an internal review (within the time limit determined by the LD) and hands it over to the CAU Head.</p> | EVA CAU/UR/SA Heads | email PRO AA FS |
| 14. Revision of the Position | <p>The UR/SA/CAU Head checks the Position on the appeal (or proposal for an internal review), amending it if necessary, and issues a consent to its handover to the LD.</p> | CAU Head | |
| 15. Decision on the appeal | <p>The LD decides whether the requests of the appellant are to be fully satisfied, in which case the procedure continues with step 14. If the appellant's requests cannot be satisfied, a position is prepared and handed over by SÚKL to the Health Ministry (MH). After the delivery of the final and conclusive</p> | LD Head | |

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| | decision of the MH, the procedure continues with step 15. | | |
| 16. Internal Review | If the Evaluator, the UR/SA Head and the legal department evaluate the possibility to use an internal review as appropriate, then the process continues with step 16. If nobody files an appeal against the result of the internal review, the procedure continues with step 17. | EVA UR/SA Head CAU Head LD employee | AA FS |
| 17. Closing of the file | The UR/SA secretariat transfers the file to the CAU secretariat. The CAU secretariat transfers the file to the archive status in the AA FS. | UR/SA secretariat | AA FS Reference registry |
| 18. Archiving of the file in the reference registry | The CAU secretariat archives the file in the CAU reference registry, stating its location. | CAU secretariat | AA FS Reference registry |

All documents posted on the official notice board bear a guaranteed electronic signature and a date stamp.

7. ANNEXES