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produced in association with Euro-Pharmat

Hospital prescription and proper dispensing by community pharmacies - Infusions

Contributors/Authors

This guide is the result of work carried out by the following industry bodies:

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Introduction

In the context where the patient's health pathway between hospital care and community care is becoming an increasingly important issue, ACL and Euro-Pharmat have come together to set up a committee of experts tasked with drafting a recommendation to facilitate proper dispensing of hospital discharge prescriptions by community pharmacies.

This interdisciplinary framework draws together skills with the potential to make a significant contribution to the proper prescription and pharmaceutical dispensing of medical devices to ensure seamless continuity of care for patients when returning home from hospital.

The flow of information between health care professionals and the coordination of those individuals are essential for this care to be properly provided. This recommendation therefore addresses the essential information that must be included in a discharge prescription to ensure proper dispensing by a community pharmacy to improve patient care, at the same time as containing the inherent health care costs.

Without challenging the patient's right to free choice, this document addresses only the Hospital / Community Pharmacy circuit.

Purpose

The purpose of this recommendation is to facilitate improved coordination between hospitals and community pharmacies for the benefit of patients and to improve the fulfillment of hospital prescriptions dispensed by community pharmacies (Prescriptions Hospitalières

¹ Report on CNAM-approved expenditure and products for 2021

Exécutées en Ville or PHEV). This recommendation has been prepared as a reminder of the rules and information essential for proper pharmaceutical dispensing and optimal patient management following the point of discharge. It outlines the care pathway, the methods used to prescribe infusions for home use, the product dispensing process and the associated care.

Targets

Simultaneously improving the relevance and efficiency of care and ensuring the proper pharmaceutical dispensing requires recommendations to be shared. The work carried out by ACL and Euro-Pharmat is intended for use by all health care professionals, including:

- Doctors -
- Pharmacists and their teams
- Nurses _
- And some of their partners, including:
- Prescription software vendors
- Dispensing software vendors

Assessments and recommendations

The practice of home infusion has highlighted the random presence of one or other of the following concepts regarding prescriptions:

• The CNAM (Caisse Nationale d'Assurance Maladie) French National Health Insurance Fund has seen an overall increase in community pharmacy expenditure relating to care provision for home infusion patients¹.

- The emergence of PERFADOM (home infusion) prescriptions partially completed for prescribers or precompleted by other stakeholders ready for signature.
- The need for improved PERFADOM billing skills among a number of stakeholders.
- The need for a higher level of knowledge around infusion generally, ranging from description methods to infusion methods and their limitations in outpatient settings, and especially in the home.
- The need for information about infusion dilution and administration
- The need to streamline administration methods (gravity drip, diffuser, active system, etc.), with particular emphasis on avoiding the abusive use of more expensive electrically powered active systems.
- The need to raise awareness among health care professionals of good catheter maintenance practices, since these are rarely covered in basic training.
- A standard 'Formulaire de prescription de perfusion à domicile Ville-Hôpital' (Community/Hospital Home Infusion Prescription Form) exists, but its use is not mandatory
- Guarded infusion that may be billed as a repurposed hydration infusion for home use.
- The possibility of prescribers being subjectively influenced in their choice of infusion administration method, disregarding the best choice on the basis of the product prescribed, infusion duration and patient physiopathological status.
- Incorrect traceability of devices and storage conditions that are not always appropriate.
- On discharge from hospital, patients may be poorly informed about the rules they should follow when wearing a catheter at home.
- The need to improve communication, collaboration and coordination between the various pharmaceutical stakeholders within the medical device circuit.

With the aim of improving care efficiency, the expert committee makes the following recommendations for home infusion:

- The need for more effective supervision of practices.
- To exercise medical control over this 4-part prescription.
- The need to communicate the importance of using the *Formulaire de Prescription de Perfusion à Domicile Ville ou Hôpital* (Community/Hospital Home Infusion Prescription Form) published in the French Official Journal on April 16, 2016, despite it not being mandatory to do so, while maintaining prescriber flexibility and freedom of choice in terms of infusion type.
- The need to make the use of the home infusion prescription form mandatory.
- The need for software vendors to provide prescribers with an on line and editable PDF version of the Community/Hospital Home Infusion Prescription Form available and downloadable from www.ameli.fr or as an

editable PDF version from <u>http://www.omedit-centre.fr/</u> portail/gallery_files/site/136/2953/5062/5228.pdf.

- The need for the prescription to specify the information required to calculate the flat-rate costs to be billed for installation/monitoring, accessories, consumables, etc.
- The e-Prescription will also make it possible to provide the Reference Guide for certain molecules
- The need to structure the hospital/community transition by identifying patient needs and prevent any treatment, discontinuation, and to do so within 2 working days prior to discharge from the health institution. The home delivery of devices must also be achieved within a compatible time frame.
- Consideration should be given to creating additional training programs and inter-professional dissemination campaigns
- The need to streamline information through the systematic transmission of documentation, including a summary of the patient's condition, suggestions for appropriate equipment, treatment and the billing options for pharmacists
- The need to ensure that prescribers comply with the proper use of pharmaceutical products on the basis of the product prescribed, infusion duration and patient physiopathological status
- Need to ensure the use of safe devices that comply with the recommendations of GERES and the LPP PERFADOM (List of Reimbursable Products and Benefits) in order to limit any risk of AEB (Accidental Exposure to Blood)

The care pathway

It is important to describe each step of the care pathway to position the role of each stakeholder in the medical device circuit.

The patient

As the recipient of the care provided, the patient is also the recipient of the prescription.

The doctor

The doctor is responsible for patient diagnosis and for writing prescriptions.

The pharmacist

The community pharmacist analyzes the prescription, properly dispenses the required products and medical devices, and bills their cost.

The paramedical staff, the majority of whom are nurses

The paramedical staff deliver care in accordance with medical prescriptions and provide patient follow-up. These professionals are permitted to prescribe under supervision² and subject to compliance with the conditions set out in the French Public Health Code (CSP).

² https://www.ameli.fr/sites/default/files/Documents/3881/document/arrete-20-mars-2012-dispositifs-medicaux-infirmiers_journal-officiel.pdf





The prescription

The quality of hospital medical device prescription has a close relationship with the efficacy of outpatient care. The prescription must meet the criteria referred to in <u>Articles</u> <u>R.5132-3 and 5 of the CSP</u> (see table in the 'Summary of prescription procedures, health product dispensing and care provision' section of this document below).

The medical prescription is the property of the patient

Dispensing

<u>Article R. 4235-48</u> of the French Public Health Code states that the pharmacist must personally supervise every stage in the dispensing process, including

- Conducting a pharmaceutical analysis of the prescription
- Providing all necessary information and advice

The dispensing process for which the pharmacist is solely responsible involves the application of appropriate and end-to-end management procedures. Medical devices also form an integral part of good dispensing practices in the context of this recommendation.

Billing

The costs of intravenous, subcutaneous and perineural infusions are reimbursed by the CNAM in accordance with the PERFADOM rates referred to in this recommendation. The pricing of consumables and accessories is based on the lists identified in the Order published in the April 16, 2016 edition of the Journal Officiel. More detailed information can be found in the 'Benefits and types of flat-rate payment' section of this recommendation.

Ensure compliance with all current LPP nomenclatures of health products

Nursing care

Within the scope of his/her own role, the nurse carries out the following actions and/or provides the following care to identify risks and ensure the comfort and safety of the patient and his/her family,³ with particular attention paid to:

- Insertion and removal of a short catheter or needle for the purpose of delivering an infusion into a superficial vein in one of the limbs or in an epicranial vein;
- Injections and infusions (excluding the first) into these catheters and into central venous catheters and incorporation of:

- a) Products other than those mentioned in the second paragraph of Article R. 4311-9
- b) Products that do not form part of the general or locoregional anesthesia techniques referred to in Article R. 4311-12

These injections and infusions are reported in writing, dated and signed by the administering nurse, and transcribed into the nursing care file

- Supervision of scarifications, injections and infusions, as referred to in Articles R. 4311-7 and R. 4311-9
- Care provided between courses of treatment for central venous lines used for home infusion, with the exception of peripherally inserted central catheter line (PICC line), PERFADOM21-ENTRETIEN-VC-SF-PICC⁴
- Care provided between courses of treatment for peripherally inserted central catheter line (PICC line), PERFADOM22-ENTRETIEN-VC-PICC-LINE ⁵
- Home disconnection of a diffuser previously supplied full and installed by the health institution, PERFADOM24-DEBRANCH-DIFF.D.⁵

Working within a protocol that complies with the definition of coordinated practice set out in Articles L. 1411-11-1, L. 1434-12, L. 6323-1 and L. 6323-3, and subject to compliance with the conditions set by legal decree, nurses may adjust the dosage of certain treatments for a given condition. The list of these conditions and treatments is set by order of the Minister of Health, and in accordance with recommendations made by the French National Authority for Health (Haute Autorité de Santé). Unless otherwise indicated by the doctor, such adjustments may be made only on the basis of the results obtained from laboratory analyses, and are subject to the patient's general practitioner being informed.⁵

³ French Public Health Code R4311-5 3°, 5° and 31° <u>https://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006913892&cidText</u> <u>e=LEGITEXT000006072665&dateTexte=20040808</u>

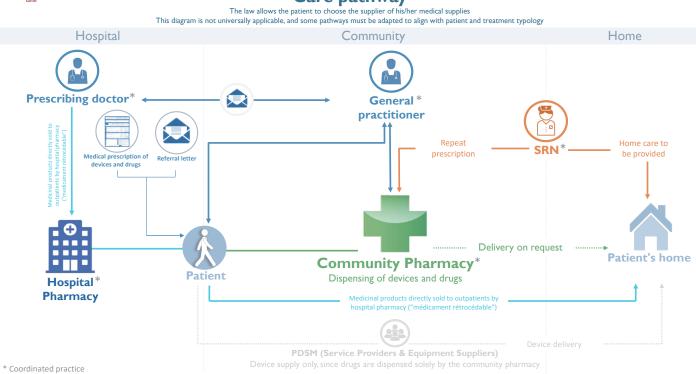
⁴ French Public Health Code <u>https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000036719759</u>

⁵ French Public Health Code https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038886488/





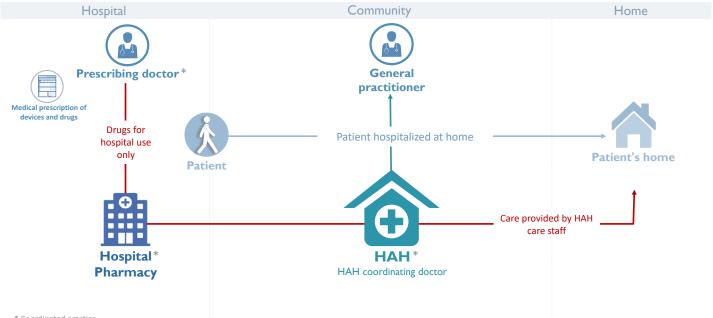




ACL

Care pathway - in the particular case of HAH

This diagram is not universally applicable, and some pathways must be adapted to align with patient and treatment typology



* Coordinated practice



*Coordinated practice⁶

The term 'coordinated practice' describes a primary or secondary care structure and/or organization within a given geographical area. It is designed by health care professionals around schemes that structure their relationships more effectively and improve coordination⁷:

Primary Care Teams (PCT): a coordinated organizational structure designed by health care professionals. PCTs bring together a number of health care professionals involved in different aspects of primary care provision with the aim of improving patient health pathways. PCTs are structured around local practice populations, and are united in delivering a health plan shared by all team members.

Regional Health Care Communities (CPTS - Communautés Professionnelles Territoriales de Santé):

are integral to population-based schemes, and are formed at the initiative of local care stakeholders, particularly community health care professionals. The plan is designed not only to improve the way which each stakeholder responds to the practice population, but also to provide a structure for responding to health needs in a given geographic area. They differ from the PCTs in that they contribute to the process of responding more effectively to the needs of a population group already known to PCT members or which is potentially part of their practice population.

Specialist Health Care Teams (SHCT): are groups of health care professionals that include doctors specializing in one or more areas other than general practice, and who opt to coordinate their care provision with all health care stakeholders (including primary care teams) in a given geographic area, based on a health plan they prepare and agree themselves. The specialist care team works alongside primary care providers to structure health care pathways.⁸

Any other form of coordinated practice may be subject to validation by the health authorities.

Prescription methods

The hospital discharge prescription is a guarantee of the quality and safety of the patient's care in the community (as an outpatient). It ensures the transmission of accurate information, proper dispensing by the pharmacist, proper care provision by nurses, and the reimbursement by compulsory health insurance and supplementary health insurance schemes. For this purpose, a *Community/ Hospital Home Infusion Prescription Form* was published as an annex to the PERFADOM listing order in the April 16, 2016 edition of the Journal Officiel. Its use is essential for the proper supply of medical devices and pharmaceutical products.

A version with interactive data entry fields for completion online and integration into prescription software is available at <u>http://www.omedit-centre.fr/portail/gallery</u> files/site/136/2953/5062/5228.pdf.

The patients is free to choose his/her own pharmacist, private nurse, general practitioner and/or service provider.

For community dispensed infusions, 4 copies of the form are printed and signed, and the appropriate checkbox ticked:⁹

- The patient;
- Stakeholders involved in the delivery of services in the community:
 - The community or hospital pharmacist for the infusion product(s)
 The service provider or community pharmacist for
- medical service(s) and devices
 The private nurse responsible for administering the infusion(s) (for information purposes)

- ⁶ <u>https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000038954739&categorieLien=id</u>
- ⁷ <u>http://circulaire.legifrance.gouv.fr/pdf/2016/12/cir_41637.pdf</u>

⁹ https://www.ameli.fr/fileadmin/user_upload/documents/Info_ameli_forfait_perfusions - Dde_FT - Annexe_4.pdf

⁸ https://www.legifrance.gouv.fr/jorf/article_jo/JORFARTI000038821303#:~:text=%C2%AB%20Une%20%C3%A9quipe%20de%20soins%20 sp%C3%A9cialis%C3%A9s,dont%20les%20%C3%A9quipes%20de%20soins



Prescription form

FORMULAIRE DE PRESCRIPTION DE PERFUSION À DOMICILE (VILLE OU HÔPITAL)

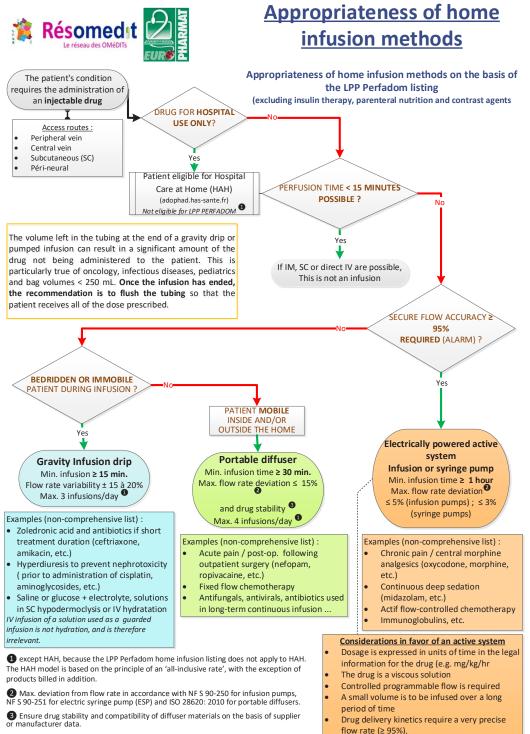
COCHER LES CASES CORRESPONDANTES DU FORMULAIRE			PATIENT					
Date de la prescription : _ _ _ _ _			Nom : Prénom :					
Initiation d'une perfusion à domicile Renouvellement ou modification			Date de naissance : _ _ _ _ _ Poids (en Kg) : _ _ , N* d'assuré : _ _ _ . _ . _ . _ . _ Soins en rapport avec une ALD					
	IDENTITÉ DU PRESO	RIPTEUR	STRUCTURE D'EXERCICE DU PRESCRIPTEUR (cabinet, éts ou centre de santé)					
Nom Préne			Raison sociale :					
	hone : _ _ _ _ _ _ _ _		Adresse :					
Ident	ifiant RPPS • : _ _ _ _ _ _ _ _ _ _		N° Finess•• géographique : _ _ _ _ _ _ N° AM••• : _ _ _ _ _ _ _					
*(répe	rtoire partagé des professionnels de santé)		**(fichier national des établisseme	**(fichier national des établissements Sanitaires et Sociaux) ***(numéro assurance maladie du prescripteur)				
	PATIENT	HÔPITAL (HAD)						
DESTINATAIRES 1 2.1 Produit(s) à perfuser : et/ou OBJET Pharmacien d'officine ou hospitalier			2.2 <u>Prestation(s) et disp</u> <u>médicaux</u> : Prestataire ou Pharmacien d'officine	Infirmier libéral en charge des Hospitalisatio				
				ignés avec le coche de la case du destinataire correspondant (cf. 1, 2.1, 2.2, et 2.3 ci-				
	a perfusion s'opère dans le cadre de l'i patient qui nécessite des soins comple					(cf. 1 et 3 ci-dessus).		
🗵 Une	e chimiothérapie réalisée avec l'appui	d'un prestataire doit se faire con	formément aux dispositions	de l'arrê	té du 20.12.2004 fixant les	conditions d'utilisation		
des	anticancereux injectables inscrits sur i	a liste « retrocession » prevue a	l'article L 5126-4 du code de	article L 5126-4 du code de la santé publique. Voie d'abord I		Mode d'administration		
	Dénomination du produit - dosage	concentration), posologie (débit e	n ml/h ou mg/h), solvant, :		eineuse centrale (VC) :	Gravité		
_	(un médicament réservé à l'usage hospite administré à domicile que dans le cadre d	ocession » ne peut être		Chambre implantable	Diffuseur			
n°					 cathéter central cathéter central à 	Système actif électrique		
JSEF					insertion périphérique	ambulatoire fixe		
ERFI				_	ri-nerveuse eineuse périphérique	En cas de <u>remplissage sous</u>		
ÀPI	Ducés d'administration d'une confu			ous-cutanée	<u>l'égide d'un établissement de</u> santé, cocher cette case :			
UIT	Durée d'administration d'une perfu	sion : (heure(s) et) Fréquence de la	minutes Djour	-		Transfuseur (transfusion de		
PRODUIT À PERFUSER n°1	Nombre total de perfusions :		ar D semaine		tretien intercure : VC sauf PICC LINE	produits sanguins labiles en Éts de transfusion sanguine)		
•	Date de début de la cure :	Date de fin de la cure : o	u Durée de la cure :		cathéter central à insertion	Si le traitement est à perfuser		
			→ jours	pe	riphérique (PICC LINE)	SEUL, cocher la case : 🗖		
<u>Est dé</u>	fini ci-dessous la cure d'un <mark>autre produit</mark> à p	erfuser, <mark>ou</mark> le nouveau <mark>cycle de cure</mark>	d'un produit déjà renseigné :		Voie d'abord	Mode d'administration		
	Dénomination du produit - dosage ((un médicament réservé à l'usage hospita			eineuse centrale (VC) :	Gravité			
.2	administré à domicile que dans le cadre d				 chambre implantable cathéter central 	 Diffuseur Système actif électrique 		
ER					cathéter central à	ambulatoire		
FUS					insertion périphérique éri-nerveuse	□ fixe		
PER				eineuse périphérique	En cas de <u>remplissage sous</u> l'égide d'un établissement de			
ΙTÀ	Durée d'administration d'une perfus	ion : (heure(s) et)	minutes		ous-cutanée	santé, cocher cette case : 🗖		
PRODUIT À PERFUSER n°2	Nombre total de perfusions :	Fréquence de la ou des perfusions : pa	□ jour □ semaine ar □ mois		ntretien intercure : VC sauf PICC LINE	Transfuseur (transfusion de produits sanguins labiles en Éts de transfusion sanguine)		
•	Date de début de la cure :	Date de fin de la cure : ou	Durée de la cure :		cathéter central à insertion riphérique (PICC LINE)	Si le traitement est à perfuser		
	_ _ / _ _ / _ _ _	_ _ . _ _ . _ _ _ _	└→ jours		inplicingue (Free Ente)	SEUL, cocher la case : 🗖		
¥			A la connaissance du prescripteur, le patient a-t-il bénéficié « en ville » d'une cure de perfusion à domicile ou de nutrition parentérale à domicile					
Comparing the second se								
C.				Non a (ou les) présente(s) perfusion(s) s'opère(-nt) « en ville », un forfait dit de nstallation pourra être pris en charge dans la limite d'un forfait de seconde				
RES		seconde in	installatio					
E P		e l'installat	nstallation par forfait de première installation, sauf proximité immédiate de installation antérieure.					
COMMENTAIRE PRESCRIPTEL				e patient a-t-il une cure de perfusion à domicile ou de nutrition				
MEN		parent	térale à domicile en cours « en ville » ? i □ Non					
WC			Si oui, si	ui, si la (ou les) présente(s) perfusion(s) s'opère(-nt) « en ville », le forfait				
S			d'access réalisée		e consommables prendra en co on du mode d'administration.	ompte l'ensemble des perfusions		
	Si d'autres cures de produits sont prescrites,							
	compléter par un ou d'autre(s) formulaire(s).							

The instructions for this form are given in the annexes to this recommendation.



Appropriateness of home infusion methods

Appropriateness of home infusion methods



If more than one administration method is possible, choose the infuser in preference to the diffuser where the duration is compatible with infusion monitoring and patient immobility.

Drug with a narrow therapeutic margin ... March 26, 2021 release



Benefits and types of flat-rate funding¹⁰:

The PERFADOM home infusion list was introduced on May 1, 2016, following publication of the April 12, 2016 Order in the April 16, 2016 edition of the Journal Officiel. Since that time, the pathology-based approach no longer applies to the home infusion funding system. It covers:

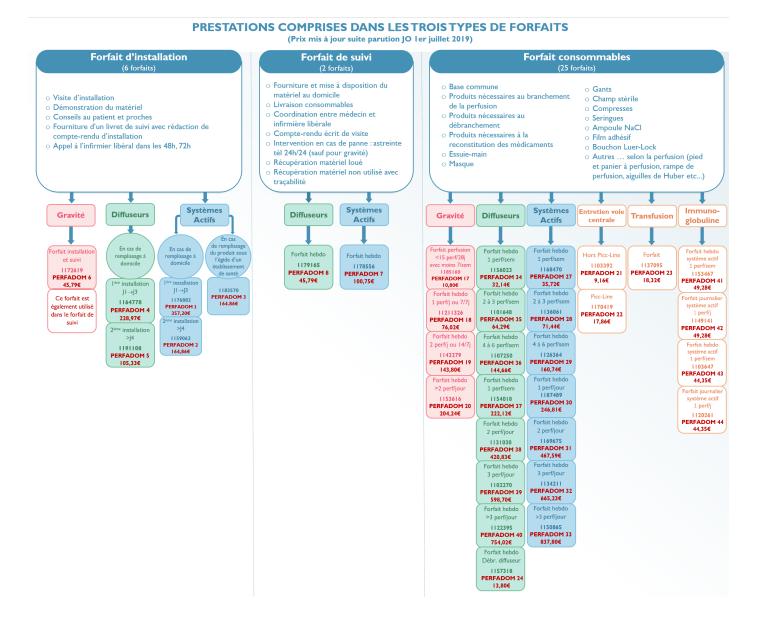
A. Funding following:

- A medical consultation
- The patient being informed about method of treatment and its administration by the prescribing doctor and/ or general practitioner and/or the private nurse.

- B. Reimbursement for infusions by intravenous, subcutaneous and perineural route, according to the following administration methods:
 - By gravity drip
 - By diffuser
 - By electrically powered active system (syringe pump / infusion pump)

C.5 types of weekly flat-rate payment:

- Installation flat-rate payments
- · Monitoring flat-rate payments
- Consumables and accessories flat-rate payments
- Flat-rate payments for care provided between courses of treatment (where central access to veins is not used for at least 7 days)
- Flat-rate payment for consumables and accessories used for the transfusion of labile blood products and immunoglobulin therapy



¹⁰ http://www.mediam.ext.cnamts.fr/ameli/cons/CIRCC/2016/CIR-12-2016.PDF



Summary table of all PERFADOM flat-rate payments by infusion type:

Туре	Nom	Code	Libellé	Tarif TTC	
	PERFADOM 6	1172619	Perfusion à domicile, forfait installation et suivi, gravité, PERFADOM 6 IS-GRAV	45,79€	
,e	PERFADOM 17	1185160	Perfusion à domicile, forfait/perfusion consomm-access, gravité, <15 perf, PERFADOM 17 -GRAV<15/28J	10,80€	
Gravité	PERFADOM 18	1121326	Perfusion à domicile, forfait hebdo consomm-access, gravité, 1 perf/jour, PERFADOM 18 -C-GRAV=1/J	76,02€	
0	PERFADOM 19	1143279	Perfusion à domicile, forfait hebdo consomm-access, gravité, 2 perf/jour, PERFADOM 19 -C-GRAV=2/J	143,80€	
	PERFADOM 20	1153616	Perfusion à domicile, forfait hebdo consomm-access, gravité, >2 perf/jour, PERFADOM 20 -C-GRAV>2/J	204,24€	
	PERFADOM 4	1164778	Perfusion à domicile, forfait installation 1, diffuseur, PERFADOM 4 - I1-DIFF	228,97€	
	PERFADOM 5	1191108	Perfusion à domicile, forfait installation 2, diffuseur, PERFADOM 5 - I2-DIFF	105,33€	
	PERFADOM 8	1179165	Perfusion à domicile, forfait hebdo suivi, diffuseur, PERFADOM 8 - S-DIFF	45,79€	
	PERFADOM 34	1156023	Perfusion à domicile, forfait hebdo consom-access, diffuseur, 1 perf/sem, PERFADOM 34 - C-DIFF=1/S	32,14€	
	PERFADOM 35	ERFADOM 35 1101648 Perfusion à domicile, forfait hebdo consom-access, diffuseur, 2 à 3 perf/sem, PERFADOM 35 - C-DIFF=2A3/S			
'n	PERFADOM 36	1107250	Perfusion à domicile, forfait hebdo consom-access, diffuseur, 4 à 6 perf/sem, PERFADOM 36 - C-DIFF=4A6/S	144,66€	
Diffuseur	PERFADOM 37	1154018	Perfusion à domicile, forfait hebdo consom-access, diffuseur, 1 perf/jour, PERFADOM 37 -C-DIFF=1/J	222,12€	
ā	PERFADOM 38	1131030	Perfusion à domicile, forfait hebdo consom-access, diffuseur, 2 perf/jour, PERFADOM 38 -C-DIFF=2/J	420,83€	
	PERFADOM 39	1102270	Perfusion à domicile, forfait hebdo consom-access, diffuseur, 3 perf/jour, PERFADOM 39 -C-DIFF=3/J	598,70€	
	PERFADOM 40	1122395	Perfusion à domicile, forfait hebdo consom-access, diffuseur, >3 perf/jour, PERFADOM 40 -C-DIFF>3/J	754,02€	
	PERFADOM 24	1157318	Perfusion à domicile, forfait hebdo consom-access, débranchement diffuseur rempli ES*, PERFADOM 24 -C-DEBR-DIFF	13,80€	
	PERFADOM 43	1103647	Perfusion à domicile, forfait hebdo consom-access, diffuseur, 1 perf/sem, PERFADOM 43 -C-DIFF IMMU-SC	44,35€	
	PERFADOM 44	1120261	Perfusion à domicile, forfait jour consom-access, diffuseur, 1 perf/jour, PERFADOM 44 -C-DIFF IMMU-IV	44,35€	
	PERFADOM 1	1176882	Perfusion à domicile, forfait installation 1, système actif électrique, PERFADOM 1 -I1-SA-ELEC	357,20€	
	PERFADOM 2	1159062	Perfusion à domicile, forfait installation 2, système actif électrique, PERFADOM 2 -12-SA-ELEC	164,86€	
	PERFADOM 3	1183570	Perfusion à domicile, forfait installation rempli par ES*, système actif électrique, PERFADOM 3 -I-REMPLI-ES-SA-ELEC	164,86€	
	PERFADOM 7	1178556	Perfusion à domicile, forfait hebdo suivi, système actif, PERFADOM 7 -SA-ELEC	100,75€	
	PERFADOM 27	1168470	Perfusion à domicile, forfait hebdo consom-access, système actif, 1 perf/sem, PERFADOM 27 - C-SA=1/S	35,72€	
Système actif	PERFADOM 28	1136061	Perfusion à domicile, forfait hebdo consom-access, système actif, 2 à 3 perf/sem, PERFADOM28 -C-SA=2A3/S	71,44€	
ème	PERFADOM 29	1126364	Perfusion à domicile, forfait hebdo consom-access, système actif, 4 à 6 perf/sem, PERFADOM29 -C-SA=4A6/S	160,74€	
Syst	PERFADOM 30	1187489	Perfusion à domicile, forfait hebdo consom-access, système actif, 1 perf/jour, PERFADOM 30 -C-SA=1/J	246,81€	
	PERFADOM 31	1169675	Perfusion à domicile, forfait hebdo consom-access, système actif, 2 perf/jour, PERFADOM 31 -C-SA=2/J	467,59€	
	PERFADOM 32	1134211	Perfusion à domicile, forfait hebdo consom-access, système actif, 3 perf/jour, PERFADOM 32 -C-SA=3/J	665,23€	
	PERFADOM 33	1150865	Perfusion à domicile, forfait hebdo consom-access, système actif, >3 perf/jour, PERFADOM 33 -C-SA>3/J	837,80€	
	PERFADOM 41	1153467	Perfusion à domicile, forfait hebdo consom-access, système actif, 1 perf/sem, PERFADOM 41 -C-SA IMMU-SC	49,28€	
	PERFADOM 42	1149141	Perfusion à domicile, forfait journ consom-access, système actif, 1 perf/jour, PERFADOM 42 -C-SA-IMMU-IV	49,28€	
en	PERFADOM 21	1103392	Perfusion à domicile, forfait d'entretien voie centrale, PERFADOM 21 - ENTRETIEN-VC	9,16€	
Entretien et Transfusion	PERFADOM 22	1170419	Perfusion à domicile, forfait d'entretien voie centrale, PERFADOM 22 - ENTRETIEN-PICC LINE	17,86€	
Tra,	PERFADOM 23	1137095	Perfusion à domicile, forfait transfusion, PERFADOM 23 -TRANSFUSION-de-PSL-en-EFS	18,32€	

*Health institution

Prescribing support resources

To ensure that hospital discharge prescriptions are appropriate for dispensing via community pharmacies, this recommendation is based on the following resources, although others are available:

Les bonnes pratiques – La perfusion (Good practices - Infusion) published by Assurance Maladie Service Médical Limousin Poitou-Charentes - October 2016¹¹

This document for health care professionals sets out good practice recommendations for infusion therapy. This memo contains general, prescription and billing information for PERFADOM.



The LPP database

The Assurance Maladie List of Products and Benefits (LPP) contains all the information required for billing LPP-coded products. It can also be searched by code, by designation or by chapter.

View the LPP database here: list of Products and Benefits by chapter (in French)

Prescription software:

One important type of resource covered by this publication is the implementation of IT solutions, particularly those software packages designed to provide assistance with prescribing medical devices by all departments of the health institution. <u>Article 32 of the Social Security Finance</u> <u>Bill</u> encourages the increased use of digital technology and sharing of information to improve the quality of care provision.

As part of encouraging this development, this recommendation could contribute to the drafting of a specification.

Dispensing software

Dispensing Software (LAD in French) uses at least one function to record the dispensing of pharmaceuticals and health products or benefits (prescription analysis, advice and dispensing) in hospitals (internal pharmacy) and community pharmacies¹².

Euro-Pharmat Proper Use Leaflets

On its website, Euro-Pharmat provides health care professionals with proper use leaflets covering a range of medical devices, and particularly those for parenteral administration.

For more information: <u>https://www.euro-pharmat.com/</u> abord-parenteral

ACLsanté database of products available via community pharmacies

The ACLsanté product database lists the infusion devices available via community pharmacies. The database contains descriptions and reimbursement data for each of these products. All this information comes directly from the supplier. The suppliers who validate ACLsante product data sheet are therefore responsible for these data and their use.

Each product is identified by a unique ACL7 index code used in information systems facilitating interaction between health care professionals.

ACLsanté makes these product data sheets available to health institutions in the form of an electronic catalog that can be used for e-Prescription.

All health institutions, their groupings and central purchasing organizations can sign an information sharing agreement with ACLsanté to obtain access to supplier-validated ACL eCatalogs.

In return, signatory health institutions agree to ask the suppliers with which they have contracts to update their data in the ACLsanté Product Database.

The end result is that hospital prescribers have a clearer overview of devices available via community pharmacies, and can also issue hospital discharge prescriptions in the knowledge that they can be easily dispensed by a community pharmacist. The information required for such prescriptions is as follows:

¹¹ <u>https://www.ameli.fr/fileadmin/user_upload/documents/memo_perfusion_janv_2017.pdf</u>

¹² <u>https://www.ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/ Logiciels-et-applications-mobiles-en-sante/Le-logiciel-ou-l-application-sante-que-je-vais-mettre-sur-le-marche-releve-t-il-du-statut-de-dispositifmedical-DM-ou-de-dispositif-medical-de-diagnostic-in-vitro-DM-DIV/Exemples-de-logiciels-et-applications-mobiles-illustrant-le-positionnementreglementaire</u>





- · Name of supplier
- 13-digit product reference code
- ACL7 index code
- Basic UDI
- Trade name
- Supplier reference
- Form
- Primary and secondary route
- · Product dimensions, diameter and/or volume
- Charrière/Gauge
- Size
- Packaging

- LPP reimbursement code
- · Medical device class
- Discontinued/replaced by
- Circuit (community/hospital)

The intention is that this electronic catalog will be made available to prescription software vendors at a future time to maximize interoperability.

For more information: info@aclsante.org



Reminders of prescription procedures, health product dispensing and provision of home infusion care

These recommendations are intended as **guidance** to help everyone understand the essential information that must be included on the (community or hospital)¹³ home infusion Prescription Form available and downloadable from the Ameli website, whether regulated under the terms of the French Public Health and Social Security Codes or recommended by the expert members of this group:

Information	Description	References
		R5132-3 7° Public Health Code
Patient identity	The patient's full name, gender, date of birth and - if relevant - height and weight	R165-38 4° Social Security Code**
Prescriber identity	The full name, position and - where applicable - title or specialty of the prescriber, as defined in Article R. 5121-91, their RPPS (shared directory of health care professionals) number where applicable, their professional address (including the word 'France'), their phone number preceded by the international dialing code '+33', their e-mail address, their signature, the date on which the prescription was written, and the name of the health institution or department	R5132-3 1° Public Health Code
Identification of the health institution	Registered name and geographic FINESS (National Directory of Health and Social Facilities) number	Decree 2010-211 Social Security Code
	The duration of treatment, number of packaging units and, where applicable, the number of repeat prescriptions	R5132-3 3° Public Health Code
Duration of treatment	Repeat prescriptions cannot cover any period longer than 12 months	R165-36 Social Security Code
	To comply with this condition, retail distributors may not supply a volume of products or services corresponding to a treatment duration longer than 30 days (one month) in a single delivery	R165-41* Social Security Code
Total duration of prescription and renewal	The total duration of the prescription or repeat prescriptions covering periods no longer than one month, subject to the maximum limit of 12 months	R165-37 Social Security Code
	The name of the health product prescribed, its frequency of use and the instructions for its use	R5132-3 2° Public Health Code
Designation of the health product	A precise prescription for the medical devices concerned, preferably quoting their trade name, regardless of whether they are registered in the List of Reimbursable Products and Benefits (LPP - Liste des Produits et des Prestations) under their generic or brand name, whatever the product. It is not legally permitted to substitute medical devices prescribed by their trade name, except with the express prior agreement of the prescriber, in the event of emergency and in the best interest of the patient (Article L. 5125-23, paragraph 1, of the French Public Health Code)	L5125-23 paragraph 1 Public Health Code
	For reimbursed health products: the description of the product or benefit concerned allowing it to be precisely correlated with the list referred to in Article L. 165-1	R165-38 1° Social Security Code**
Quantity of the health product concerned	The quantity of the health product or the number of packaging units required, based on the regulated duration of prescription	R165-38 2° Social Security Code**
Special conditions applying to the health product	Where applicable, any special conditions applying to the use of the health product or service may govern its inclusion or otherwise in the said list.	R165-38 3° Social Security Code**
Quantity to be provided	To enable funding of health products registered on the list referred to in Article L. 165-1 that are available in different packaging units, the retail distributor provides the patient with the most economical packaging compatible with the information shown on the prescription	R165-39 Social Security Code
Prescription validity	The prescription validity period expires when all the health products and services covered by the total duration of prescription have been dispensed In order for the health product to be reimbursed, it must be dispensed for the first time within 6 months of the prescription date	R165-40 Social Security Code
Prescription of health products and nursing procedures	It is recommended that the prescription for nursing care should be on the same document as the health product prescription.	Expert recommendation

* However, health products available in packaging corresponding to a duration of treatment exceeding one month may be dispensed for that period up to the maximum limit of the remaining duration of prescription, provided that it is the most economical packaging compatible with the information shown on the prescription.

** LPP reimbursement

Take account of compliance with the current LPP health product reimbursement listings and of any changes shown on the Ameli website <u>www.ameli.fr</u>

¹³ https://www.ameli.fr/fileadmin/user_upload/documents/Info_ameli_forfait_perfusions - Dde FT - Annexe_4.pdf

PHARMAT

Reference documents and databases

- 1. 1. French Public Health Code fundamental principle of free choice for patients Available from: <u>https://www.legifrance.gouv.fr/codes/article_lc/</u> <u>LEGIARTI000025843591/</u>
- The Order of April 12, 2016, published in the April 16, 2016 edition of the Journal Officiel introducing changes to the conditions governing the inclusion of medical devices for home parenteral nutrition and associated benefits in the list of products and benefits provided for in Article L. 165-1 of the Social Security Code. Available from: <u>https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000</u> 032407252?r=sh6EnX8tKI
- 3. The order of June 26, 2019 introducing changes to the terms and conditions governing reimbursement for home infusion medical devices and associated benefits listed in Title I of the list of products and benefits provided for in Article L. 165-1 of the Social Security Code

https://www.legifrance.gouv.fr/jorf/id/ JORFTEXT000038689260

 French Social Security Code – Decree 2012-860 of July 5, 2012 on the terms and conditions for prescribing and issuing products and benefits included on the list provided for in Article L. 165-1 of the French Social Security Code. JORF July 7, 2012. Available from: https://www.logifrance.gouv.fr/affichTexte.do2cidText

https://www.legifrance.gouv.fr/affichTexte.do?cidText e=JORFTEXT000026152057&categorieLien=id

- 5. French Public Health Code Article R5132-3 defines the information to be included on prescriptions. Available from: <u>https://www.legifrance.gouv.fr/affichCodeArticle.do?i</u> <u>dArticle=LEGIARTI000028393053&cidTexte=LEGIT</u> <u>EXT000006072665&dateTexte=20131228</u>
- French Public Health Code Order of March 20, 2012, establishing the list of medical devices that may be prescribed by nurses. JORF March 30, 2012. Available from: <u>https://www.legifrance.gouv.fr/affichTexte.do?cidText</u> <u>e=JORFTEXT000025592708&categorieLien=id</u>
- Public Health Code Article L4311-1 defines the process by which nurses may be authorized to adapt the dosage of certain treatments for a given pathology. Available from: <u>https://www.legifrance.gouv.fr/codes/article_lc/ LEGIARTI000038886488/</u>
- French Social Security Code Decree of March 14, 2018 introducing changes to the terms and conditions governing the reimbursement of home infusion medical devices and associated benefits listed in Title I of the

list of products and benefits provided for in Article L. 165-1 of the Social Security Code. Available from: <u>https://www.legifrance.gouv.fr/jorf/id/</u> JORFTEXT000036719759

- 9. French Public Health Code Article R4235-48 defines the dispensing process. Available from: <u>https://www.legifrance.gouv.fr/affichCodeArticle.do?i</u> <u>dArticle=LEGIARTI000006913703&cidTexte=LEGIT</u> <u>EXT000006072665&dateTexte=20040808</u>
- French Social Security Code Decree No. 2017-584 of April 20, 2017 setting the terms and conditions governing implementation of the CAQES (contrat d'amélioration de la qualité et de l'efficience des soins - Health Care Quality and Efficiency Improvement Contract). JORF April 22, 2017. Available from: <u>https://www.legifrance.gouv.fr/affichTexte.do?cidText</u> <u>e=JORFTEXT000034453909&categorieLien=id</u>
- French Social Security Code Order of April 27, 2017 relating to the standard CAQES referred to in Article L. 162-30-2 of the Social Security Code. JORF April 30, 2017. Available from: <u>https://www.legifrance.gouv.fr/affichTexte.do?cidText</u> <u>e=JORFTEXT000034517810&categorieLien=id</u>
- Social Security Code Order of December 12, 2018, setting the standards for care appropriateness, quality, safety and thresholds expressed in terms of volume or health insurance expenditure, as referred to in Article L. 162-30-3 of the French Social Security Code. JORF December 12, 2018. Available from: <u>https://www.legifrance.gouv.fr/affichTexte.do?cidText</u> <u>e=JORFTEXT000037846009</u>
- 13. Expense and income report for 2021. Improving the health care system quality and controlling expenditure: Assurance Maladie proposals for 2021. Accessed 01/08/2021 Available from: <u>https://www.ameli.fr/fileadmin/user_upload/</u> <u>documents/2020-07_rapport-propositions-</u> <u>pour-2021_assurance-maladie.pdf</u>
- 14. Community/Hospital Home Infusion Prescription Form in editable PDF form. Accessed 02/08/2021. Available from:

http://www.omedit-centre.fr/portail/gallery_files/ site/136/2953/5062/5228.pdf

- 15. Euro-Pharmat: Proper use leaflets covering a range of medical devices, and particularly those for parenteral access route. Accessed 2/21/2020. Available from: https://www.euro-pharmat.com/abord-parenteral
- 16. ACLsanté product database: provision of eCatalogs for products marketed through community pharmacies, and containing descriptions and reimbursement information. Available from: www. aclsante.org



Glossary

CNAM: Caisse Nationale d'Assurance Maladie (National Health Insurance Fund)

Medical device: any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products are also deemed to be medical devices:

- · Devices for the control or support of conception
- Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point¹⁴.

Safety devices: these are invasive devices with integrated systems for covering the sharp part of the device (needle or blade) after use. Most are medical devices (MD). Safety devices may also be solutions developed to limit injection-related risks. This type of devices is being used with increasing frequency and continually improved on the basis of studies demonstrating their effectiveness and of new regulations¹⁵.

FINESS: Fichier National des Etablissements Sanitaires et Sociaux (National Directory of Health and Social Facilities) . <u>http://finess.sante.gouv.fr/fininter/jsp/index.jsp</u>

LPPR: Liste des Produits et Prestations Remboursables (List of Reimbursable Products and Benefits) <u>http://www.codage.ext.cnamts.fr/codif/tips/index_presentation.php?p_site=AMELI</u>

Medicinal product directly sold to outpatients by hospital pharmacy: ("médicament rétrocédable"): in accordance with Article L.5126-4 of the French Public Health Code, a drug with Marketing Authorization (MA) or cohort temporary authorisation for use (ATU) that may, for public health reasons, be retailed to the public. The list of these specific medicinal products is compiled by the Minister of Health on the basis of recommendations or proposals put forward by the National Agency for Medicines Safety (ANSM)¹⁶.

Drugs for hospital use only: these are drugs prescribed, dispensed and administered exclusively during hospitalization¹⁷ (unless otherwise stated in the Marketing Authorization) or in the patient's home as part of outpatient home care or home dialysis¹⁸.

Home infusion: Home infusion enables drugs to be administered to a patient by means of a slow, prolonged, continuous or discontinuous process of injection. An infusion is therefore a preparation including one or more molecules (if miscible and mutually compatible) diluted in a solvent and contained in an administration device connected to a tubing. Direct intravenous or subcutaneous injections lasting less than 15 minutes are not deemed to be infusions, and are therefore excluded from the scope of the 'home infusion' list. Similarly, infusions administered by diffuser must last 30 minutes or more, while infusion by means of an electrically powered active system must last 60 minutes or longer.

PERFADOM: the list of applicable home infusions since 05/01/2016. PERFADOM is an abbreviation of the French term *perfusion à domicile* (home infusion), which refers directly to the legal text published in the April 16, 2016 edition of the Journal Officiel.

RPPS: Répertoire Partagé des Professionnels de Santé (Shared Directory of Health Care Professionals)²⁰

¹⁵ <u>https://www.geres.org/cadre-general-materiels-de-protection/securite-des-gestes-invasifs/</u>

- ¹⁸ https://www.legifrance.gouv.fr/codes/id/LEGIARTI000034102393/2017-03-01
- ¹⁹ https://www.ameli.fr/fileadmin/user_upload/documents/info_medecins_perfusions20160720.pdf

¹⁴ https://eur-lex.europa.eu/legal-content/FR/TXT/HTML/?uri=CELEX:32017R0745&from=FR

¹⁶ <u>https://solidarites-sante.gouv.fr/soins-et-maladies/medicaments/professionnels-de-sante/prescription-et-dispensation/article/medicaments-retrocedes-retrocession</u>

¹⁷ https://solidarites-sante.gouv.fr/IMG/pdf/medicaments-3.pdf

²⁰ <u>https://annuaire.sante.fr/web/site-pro/recherche/rechercheDetaillee</u>



Summary

In the context where the patient's health pathway between hospital care and community care is becoming an increasingly important issue, ACL and Euro-Pharmat have come together to set up a committee of experts. Its goal is to make a significant contribution to the proper prescription and dispensing of medical devices to ensure seamless continuity of care for patients when returning home from hospital. This recommendation addresses the essential information that must be included in a discharge prescription to ensure proper dispensing by a community pharmacy to improve patient care, at the same time as containing the inherent health care costs. It presents an outline of the care pathway, the methods used to prescribe infusions for dispensing via community pharmacies, the dispensing of infusions and associated care.

KEY WORDS

ACLsanté Product Database – Good Practices – Catheter – Coordination – Pharmaceutical Continuity – CPTS (Regional Health Care Communities) – Diffuser – Dispensing – Medical Device – Safe Device – MD – Home–ePrescription–Efficiency–Primary Care Team– Health Care Team–Assessment – Coordinated Practice – Billing – Proper use of medicines leaflets – Flat-rate – Seriousness – HAH (Hospital Care at Home) – Hospital – Nurse – Dispensing Software – Prescription Software – Drugs – Administration Methods – Prescription – Care Pathway – Home Infusion – PERFADOM – Pharmacy – Advice – Prescription – Recommendation – Nursing Care – Active System – Community





ANNEX: Community/Hospital Home Infusion Prescription Form

Identity of the prescriber and his/her practice **setting** (surgery, health institution, health center, etc.):

- In the 'prescriber identity' box: enter the (Shared Directory of Health Care Professionals) number
- In the 'practice setting' box:
 - Where the prescription is being issued by a doctor on the staff of a health institution or health center: enter the FINESS (National Directory of Health and Social Facilities) number of the institution;
 - Where the prescription is being issued by a private practitioner: enter the Assurance Maladie registered number of the doctor whose name appears on the prescription.

Recipients and/or purpose: Multiple copies of the Community/Hospital Home Infusion Prescription (HAH) form must be printed, although the actual number of copies depends on where the benefit is delivered 'in the community' or by HAH (patients who require complex and multidisciplinary care are always HAH patients).

- For **community dispensed** infusions, 4 copies of the form are printed and signed, and the appropriate checkbox is ticked:
 - The patient;
 - Stakeholders involved in the delivery of services in the community:
 - The community or hospital pharmacist for the infusion product(s);
 - o The community pharmacist for the benefit(s) and medical devices;
 - o The private nurse responsible for administering the infusion(s) (for information purposes);
- If the infusion is intended for **HAH** care, 2 copies of the form are printed and signed, and the appropriate checkbox is ticked:
 - The patient;
 - HAH;

If the treatment involves more than 2 courses of infusion(s) or cycles of infusion(s), additional prescription form(s) must be completed.

Courses of product administration:

Only one drug or solution is to be prescribed in each of the 'product' boxes of the form, however, any associated products (electrolytes, vitamins, etc.) in the same container (bag, vial, etc.) must also be entered.

A drug intended exclusively for hospital use and not shown on the list provided for in Article L 5126-4 of the Public Health Code may be home administered only within the HAH care framework.

Product name, dose and dosage

Where infusion is intermittent, the dosage should correspond directly with the dose administered per injection, unless otherwise stated.

Where continuous infusion is delivered by an electrically powered active system, the product concentration, dose and flow rate (in mL/hr or mg/ hr) are entered.

Duration of administration

Where infusion is intermittent, the duration of administration is entered in minutes or hours.

Where infusion is continuous infusion, the word 'continuous' is entered.

Solvent

If the product is a solute (NaCl 0.9% or G5%) or if no solvent is necessary, this information is not required. With the exception of these cases, the nature of the solvent compatible with the treatment must be indicated, together with the volume of dilutions.

Where a syringe or diffuser is used, the acronym Q.S.P. (quantity sufficient for) can be used to adjust the concentration.

Duration of treatment

The treatment start date is that of the first day of home treatment administration.

The treatment end date must also be entered, but where this is not available, the duration of treatment

Access routes:

Check only 1 of the following 4 boxes: central vein, peripheral vein, subcutaneous and perineural. Only treatments administered via the option selected are to be prescribed using this form.

For central vein administration:

- It must be specified whether it is an implantable chamber, a central venous catheter or a peripherally inserted central catheter (PICC Line).
- Where a central line infusion is delivered in multiple treatment cycles, and the implanted line is not used for 7 days or more during or following the described course treatment, one of the **flat-rate maintenance** charges for this central line may be reimbursed. Check the box and indicate whether the means of delivery is a 'PICC Line' or otherwise.

Method of administration

Select only one method of administration. In cases where more than one method of administration may be appropriate for infusion of the product, the prescriber should, whenever possible, choose gravity drip infusion in preference to a diffuser or electrically powered active system, and a diffuser in preference to an electrically powered active system; this choice should take account of how the method of administration would impact on patient mobility or independence.

Diffuser infusions must last for 30 minutes for longer. Generally speaking, infusions delivered by electrically



powered active systems must last for 60 minutes or longer, except in special cases, such as the nature of the products to be infused, the need for a specific flow rate or a succession of infusions. Where this minimum 60-minute duration is waived for infusion using an electrically powered active system, the prescribing doctor will notify the Assurance Maladie medical advisor of this fact in an explanatory letter.

Where treatment is administered using an electrically powered active system, specify whether it is of the 'fixed' or 'outpatient' type.

Where treatment for administration by diffuser or electrically powered active system is prepared and filled in a health institution, the appropriate box must be ticked.

Infusion drug only

Where, for a given access route, the assessment of the prescribing doctor is that a drug should be infused alone because of a risk of interaction or incompatibility with another product infused via the same route, the corresponding box must be ticked. Where this is the case, a treatment regimen must - under all circumstances and without exception - be prepared and provided to the nurse responsible for delivering the care.

Comments

<u>No treatment should be prescribed in this section</u>. Where more than two treatments are prescribed for a given access route, another form must be used.

Where necessary, the prescribing doctor may add to the prescription by specifying the materials required to ensure safe administration of the products.

When a product is to be infused alone or if the multiplicity of treatments makes it necessary to do so, a treatment regimen specifying administration start times (or device replacement in the case of continuous administration) may be entered in this box.