



REVIEW

# Outpatient Parenteral Antimicrobial Therapy (OPAT) in Italy: A Scoping Review

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## ABSTRACT

**Introduction:** Outpatient parenteral antimicrobial therapy (OPAT) enables effective infection management outside hospital settings, offering clinical and economic benefits. While widely adopted internationally, its implementation in

Italy remains fragmented. This study aimed to systematically map the use of OPAT in Italy to identify research and policy priorities.

**Methods:** A scoping review was conducted following the Joanna Briggs Institute methodology and Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for scoping reviews guidelines. The protocol was registered on the Open Science Framework (<https://doi.org/10.17605/OSF.IO/GX8S6>) in August 2025. Searches were performed across PubMed,

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Cumulative Index to Nursing and Allied Health Literature, Web of Science, and Scopus. Eligible studies included primary research on OPAT in Italy, with no restrictions on publication date or language. Data extraction focused on study characteristics, OPAT indications, antimicrobial agents, delivery models, and outcomes.

**Results:** Twenty-three studies were included, mostly observational and single-center, published between 2000 and 2025. OPAT was primarily delivered at home or in infusion centers. The most frequent indications were infections of bone and joint, skin and soft tissue, and the respiratory tract. Ceftriaxone was the most used antimicrobial. Delivery was mainly intravenous, often via elastomeric pumps and peripheral or central venous access. Reported outcomes were generally favorable, with cure or improvement rates exceeding 90% in several studies. Adverse events were infrequent, mostly associated with drug reactions or catheter-related complications. Patient satisfaction was consistently high. Economic evaluations were limited but suggested cost savings primarily driven by reductions in hospital stays.

**Conclusions:** OPAT is feasible and increasingly used in Italy, but remains inconsistently implemented across regions. Broader adoption would benefit from national guidance, standardized protocols, and integrated stewardship frameworks. Future research should address comparative and cost-effectiveness, as well as equitable access, to support systematic scale-up aligned with national health priorities on antimicrobial resistance and community-based care.

**Keywords:** Outpatientparenteralantimicrobial therapy; OPAT; Italy; Antimicrobial stewardship; Infection management; Community care; Scoping review

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### Key Summary Points

This scoping review maps outpatient parenteral antimicrobial therapy (OPAT) in Italy, describing populations, indications, antimicrobials, delivery models, and outcomes.

OPAT is delivered mainly at home and in infusion centers, most often for bone and joint, skin/soft-tissue, and respiratory infections, with  $\beta$ -lactams, in particular ceftriaxone, administered via intravenous routes including elastomeric pumps.

Although outcome definitions, safety reporting and follow-up are heterogeneous and largely observational, clinical outcomes are generally favorable, with cure or improvement frequently over 90%, adverse events uncommon and predominantly drug- or device-related, and patient satisfaction and adherence high.

OPAT models varied across regions with limited stewardship-linked and multidisciplinary programmes, generally involving nurses and general practitioners, while OPAT-specific national guidance and standardized protocols are still not documented the literature.

## INTRODUCTION

Outpatient parenteral antimicrobial therapy (OPAT) is commonly defined as the administration of parenteral antimicrobial therapy in at least two doses on different days without hospitalization [1]. OPAT was first described in the United States (US) over 50 years ago in children with cystic fibrosis to allow prolonged intravenous therapy while minimizing inpatient stays [2]. Early adoption in the US was facilitated by gaps in insurance coverage and cost pressures, which incentivized the discharge of clinically stable patients to receive parenteral antibiotics in

outpatient clinics or at home under structured, multidisciplinary oversight [3].

Over subsequent decades, OPAT has expanded internationally, with substantial variation in terms of financing, delivery sites, antimicrobial selection, and device use. Several drivers have strengthened the rationale for OPAT implementation. Demographic and epidemiological trends have increased demand for acute inpatient care and a rising prevalence of chronic diseases, contributing to overwhelm available bed capacity and workforce supply [4, 5]. Inpatient management of parenteral therapy entails avoidable exposure to healthcare-associated infections (HAIs) and colonization by antimicrobial-resistant organisms, with recognized burden across European hospitals [6, 7]. In addition, from an economic perspective, OPAT can reduce costs compared to inpatient care and improve hospital throughput by freeing bed-days for other admissions [8, 9]. As a result, OPAT improves quality of life compared to prolonged hospitalization by allowing patients to return home, resume daily activities, and experience reduced psychological burden. It is associated with increased QALYs without compromising clinical outcomes [10, 11].

The main indications for OPAT include soft tissue infections [12, 13], bone and joint infections [14, 15], and infective endocarditis [16, 17]. This approach is also described for numerous other infections, including urinary and respiratory tract infections caused by difficult to treat organism and central nervous system infections [18, 19].

Patients referred for outpatient treatment need to be clinically stable, both in terms of their general condition and their infection [20]. Studies indicate that OPAT is clinically safe and associated with favorable clinical outcomes alongside high patient satisfaction [5, 21, 22]. Although high-quality comparative trials remain limited, systematic reviews report no significant differences in key outcomes between OPAT and inpatient parenteral therapy when services are appropriately managed [23, 24]. Despite its benefits, the use and availability of OPAT remain heterogeneous internationally [24] because models are tailored to patient preferences and capabilities, health-system design and financing,

geography, antimicrobial availability, delivery technologies, local service infrastructure [25] and, overall, national regulation. OPAT programs are generally integrated into national regulatory frameworks. In Italy, Presidential Decree No. 384 [26] allows hospitals to provide medications for home use, including those restricted to hospital settings, as part of scheduled treatment cycles that serve as alternatives to day hospital care. More recently, the National Recovery and Resilience Plan (2021–2026), emphasizes the enhancement of primary and community care, promoting the home as the preferred setting for treatment and supporting the expansion of OPAT services. Actually, OPAT operates within a regionalized National Health Service that guarantees universal coverage while delegating substantial organizational responsibility to the regions, resulting in locally adapted models pathways, and variable capacity across settings [27]. However, to inform policies and address this change, to the best of our knowledge, no systematic reviews have summarized the nationwide characterization of OPAT in Italy. Therefore, this scoping review aims to systematically map the use of OPAT in Italy, describing patient populations, indications, antimicrobial agents, administration modalities and outcomes related to identifying the evidence gaps and research and policy priorities.

## METHODS

A scoping review following the Joanna Briggs Institute (JBI) methodology [28], and reported here in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for scoping reviews (PRISMA-ScR) guidelines (Supplementary Table 1) [29]. The review protocol was developed collaboratively, agreed upon by all researchers, and registered on the Open Science Framework (<https://doi.org/10.17605/OSF.IO/GX8S6>) in August 2025.

(a) *Defining and aligning the objective and question.* The research question was formulated according to the aim of the study, using the Population, Concept, and Context (PCC) framework recommended by the JBI Manual

for Evidence Synthesis [28]. In this review, the Population was defined as individuals with infectious disease not hospitalized; the Concept as OPAT; and the Context as the Italian healthcare setting. Accordingly, the research question was: what evidence is available on the use of OPAT in Italy?

*(b) Eligibility criteria.* Eligibility criteria were defined considering the study population, the type of intervention, the clinical setting, and the geographical focus. Studies were included if they: (a) were primary research studies of any design (interventional, observational, case series or case reports, including those published as abstracts); (b) involved individuals, adults and/or paediatric, receiving parenteral antimicrobial therapy in an out-of-hospital setting; and (c) reported data and/or experience from Italy. Studies were excluded if they were secondary research (e.g., systematic reviews), protocols, editorials, or commentaries. No restrictions in language or publication date were applied.

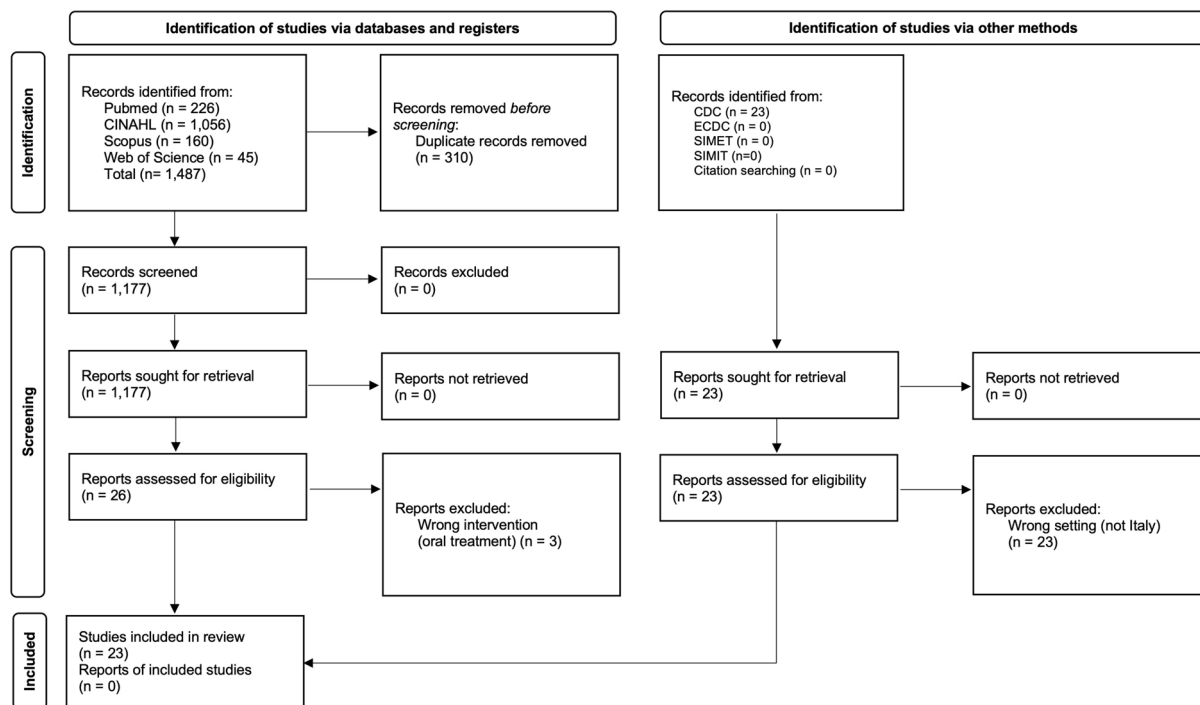
*(c) Evidence searching, selection, data extraction, and presentation of the evidence.* The research team met regularly prior to initiation, throughout the review process, and upon completion of each phase. The approach to the search strategy, study selection, data extraction, and evidence presentation was discussed in advance and planned in the registered protocol. At each stage, discrepancies were addressed through discussion meetings and resolved by consensus. An initial exploratory search was conducted, limited to two databases, PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL), by three researchers (CM, SG, FP). The analysis of the text words contained in the title and abstract, the keywords and index terms of retrieved papers, and related Medical Subject Headings (MeSH), were identified, such as “OPAT”, “outpatient” and “Italy”. All terms were combined using Boolean operators in accordance with the PCC framework to develop complete search strings for each database (Supplementary Table 2). The subsequent comprehensive search was then undertaken in four databases: PubMed, CINAHL, Web of Science, and Scopus. To broaden coverage, we also searched grey literature and targeted websites of professional and public health bodies (Centers for Disease Control and Prevention,

European Centre for Disease Prevention and Control, Società Italiana di Medicina Tropicale e Salute Globale, Società Italiana di Malattie Infettive e Tropicali) and performed backward and forward citation searching. All searches were completed in September 2025. Search results were managed using Rayyan.ai [30]. Duplicate records were manually checked and removed. Screening then proceeded in two stages (title/abstract followed by full text) conducted independently by two reviewers (CM, SG), with disagreements resolved by a third reviewer (FP). The study selection process (identification, screening, eligibility, inclusion) is illustrated in the PRISMA 2020 flow diagram [31] in Fig. 1.

The charting form was drafted during the protocol stage, piloted on one included study [32], and then finalized. Data collected included (a) first author, title, year and journal of publication, (b) study design, setting, sample size, age of participant and personnel involved in OPAT (both professionals and non-professionals); (c) type of infection, isolated microorganisms, drug, dose, schedule and length for OPAT, route, device and infusion system, and (d) outcomes related to OPAT (clinical, safety, pharmacological, patient-reported, organizational and economic).

Data from all included studies were then extracted independently by two researchers (CM, FP) and verified by a third (SG). Missing data were recorded as ‘Not reported’. Complete extracted data are provided in Supplementary Table 3.

*(d) Analysis of the evidence, presentation of the results and summary of the findings.* Data from the included studies were analyzed descriptively. Frequencies were reported, and findings were grouped according to shared characteristics. In line with the aim of mapping available evidence, no comparative or inferential analyses were undertaken, as assessing intervention effectiveness was not appropriate. Findings were presented descriptively. Three tabular summaries were developed: (a) characteristics of included studies (year, design, setting, and professionals and non-professionals involved for OPAT); (b) Factors related to the OPAT treatment: the type of infections, the microorganism isolated and the antimicrobial agents and (c) Main



**Fig. 1** Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources [31]. *CDC* Centers for Disease Control and Prevention; *CINAHL* Cumulative Index to Nursing and

Allied Health Literature; *ECDC* European Centre for Disease Prevention and Control; *SIMET* Società Italiana di Medicina Tropicale e Salute Globale; *SIMIT* Società Italiana di Malattie Infettive e Tropicali

outcomes: clinical, safety, pharmacological, patient-reported, organizational, and economic. Evidence from the included studies was synthesized and discussed by the research team. In the discussion section, findings were interpreted in relation to regulations, existing literature, and practice outcomes.

This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

## RESULTS

A total of 23 studies were included. The main characteristics, as the distribution of publications over time, study designs, and reported OPAT settings are summarized in

Table 1. Studies were published from 2000 [33] to 2025 [32]. Eight studies (34.8%), published between 2000 and 2005, represented the largest cluster in the early period. This was followed by a stable trend, with three studies (13.0%) each in the periods 2006–2010 and 2011–2015, and two studies (8.7%) between 2016 and 2020. A marked increase was then observed in the most recent period, 2021–2025, with seven studies (30.4%). The majority ( $n = 18$ ) were conducted in Italy, while five were multinational studies [34–38].

Regarding study design, only one study (4.3%) was interventional [39], while the others were observational: 14 (60.9%) were cohort, three (13.0%) were case series [40–42], three (13.0%) were case reports [32, 43, 44] and two (8.7%) were ecological [38, 45].

With respect to OPAT delivery settings, some studies described a single setting, whereas others reported multiple settings within the same

**Table 1** Main characteristics of included studies

Categories	Factors	No. of studies (%) <sup>a</sup>	References
Years of publication			
	2000–2005	8 (34.9)	[33, 35, 39, 42, 45–47, 52]
	2006–2010	3 (13.0)	[48, 53, 54]
	2011–2015	3 (13.0)	[34, 36, 38]
	2016–2020	2 (8.7)	[37, 49]
	2021–2025	7 (30.4)	[32, 40, 41, 43, 44, 50, 51]
Study design			
Interventional	Pilot	1 (4.3)	[39]
Observational	Cohort	14 (60.9)	[33–37, 41, 46–50, 52–54]
	Case series	3 (13.0)	[40–42]
	Case report	3 (13.0)	[32, 43, 44]
	Ecological	2 (8.8)	[38, 45]
Setting for OPAT <sup>b</sup>			
	Home	12 (52.2)	[32, 33, 35, 37, 43, 46–52]
	Infusion center	11 (47.8)	[35, 39, 41, 42, 47–51, 53, 54]
	Clinic	5 (21.7)	[41, 48, 50, 51, 54]
	Care facility	3 (13.0)	[40, 48, 54]
Professionals/not professionals <sup>b</sup>			
	Nurse	11 (47.8)	[32, 35, 40, 41, 46–50, 51, 54]
	General practitioner/physician	10 (30.4)	[32, 33, 35, 40, 45–49, 54]
	Infectious disease specialist	7 (30.4)	[37, 40, 41, 44, 46, 50, 51]
	Pharmacist/pharmacologist	4 (17.4)	[40, 41, 50, 51]
	Family members	6 (26.1)	[35, 46–49, 54]
	Caregivers	2 (8.7)	[40, 41]

OPAT outpatient parenteral antimicrobial therapy

<sup>a</sup>Percentages are shares of the 23 included studies

<sup>b</sup>Factors are not mutually exclusive

study; categories are therefore not mutually exclusive, and percentages reflect the proportion of included studies mentioning each setting. The larger group of studies ( $n=12$ , 52.2%) described OPAT conducted in home [32, 33, 35, 37, 43, 46–52] and in infusion centers ( $n=11$ , 47.8%), both inside or outside the hospitals [35, 39, 41,

42, 47–51, 53, 54]. Clinic and care facility were reported respectively in five (21.7%) [41, 48, 50, 51, 54] and three (13.0%) [40, 48, 54] studies, respectively.

The number of participants varied, ranging from one [32, 43, 44] to 5509 [37]. The age of participants ranged from 6 [33] to 91 years

[50]. Only one study focused on a pediatric population [33].

The most frequent professionals involved in OPAT were nurses ( $n=11$ , 47.8%) [32, 35, 40, 41, 46–51, 54] and general practitioners or physicians ( $n=10$ , 30.4%) [32, 33, 35, 40, 45–49, 54]. The infectious disease specialists were involved in OPAT in approximately one-third of studies ( $n=7$ , 30.4%) [37, 40, 41, 44, 46, 50, 51]. Other professionals, like pharmacists ( $n=4$ , 17.4%) [40, 41, 50, 51] and vascular access team ( $n=1$ , 4.3%) [50] were less cited. Among non-professional participants in OPAT, some studies reported the involvement of patients' family members ( $n=6$ , 26.1%) [35, 46–49, 54] and caregivers ( $n=2$ , 8.7%) [40, 41].

### Infections, Microorganisms, and Antimicrobial Therapy

The types of infections treated with OPAT, the microorganisms identified, and the antimicrobial agents administered are summarized in Table 2.

The main infections reported in the studies concern bone and joint ( $n=12$ , 52.2%), skin and soft tissue ( $n=10$ , 43.5%), and respiratory tract ( $n=9$ , 39.1%). Endocarditis ( $n=5$ , 21.7%), bloodstream infections ( $n=3$ , 13.0%), diabetic foot infection ( $n=1$ , 4.3%) and HAIs ( $n=1$ , 4.3%) were less frequently reported.

Data on microorganisms were available in just over half of the included studies (13 out of 23). Among the pathogens identified, the most frequently reported were *Pseudomonas aeruginosa* ( $n=5$ , 21.7%), followed by *Enterobacterales* ( $n=3$ , 13.0%), *Staphylococcus* spp. ( $n=3$ , 13.0%), and *Streptococcus* spp. ( $n=2$ , 8.7%). Several studies also reported antimicrobial resistance patterns, including multidrug-resistant organisms [41], methicillin-resistant *Staphylococcus aureus* (MRSA) [34, 36, 53], and carbapenem-resistant strains [44].

A broad spectrum of antimicrobial agents was administered, most belonging to the  $\beta$ -lactam class. Among these, third-generation cephalosporins were the most frequently used, in particular ceftriaxone ( $n=12$ , 52.2%). More recently introduced agents, such as ceftolozane/

tazobactam [41, 51], ertapenem [40, 50], and cefiderocol [32], were described in the most recent publications. Among glycopeptides, teicoplanin was the most widely used, reported in eleven (47.8%) studies [34, 35, 39, 40, 42, 47–50, 53, 54]. The lipopeptide daptomycin was documented in four studies (17.4%) [34, 36, 40, 50], and the aminoglycoside gentamicin in three (13.0%) [42, 50, 54].

Antimicrobial administration in OPAT was predominantly reported via the intravenous route, while intramuscular administration was less commonly documented. Infusion schedules included intermittent dosing [39], rapid injection [36], and continuous infusions [32]. Vascular devices used included peripheral catheters [35, 48, 54], midlines [32], and central catheters such as peripherally inserted central catheters (PICCs) [35, 44, 54] and totally implanted catheters [48, 54]. Elastomeric pumps were the most frequently reported for continuous intravenous infusions [32, 40, 41, 44, 50, 51].

### Outcomes Related to OPAT

The main characteristics of outcomes related to OPAT are reported in Table 3, classified as clinical, safety, pharmacological, patient-reported, organizational, and economic.

#### Clinical Outcomes

From a clinical perspective, cure or clinical cure was explicitly reported in 13 (56.5%) studies [33, 39, 41, 42, 46–54]. Two studies reported cure rates of 100% [40, 42], while seven documented high cure rates, equal to or exceeding 90% [35, 39, 46, 48–50, 53]. Improvement, defined as clinical improvement or the absence of signs and symptoms at follow-up, was reported in several studies ( $n=11$ , 47.8%), with rates varying between 3.2% [47] to 95.1% [35, 49]. Relapse rates varied between 2.1% [51] to 3.7% [40], whereas hospital re-admission rates ranged from 0% [50] to 10.6% [51]. Treatment failure was reported in six studies [35, 39, 41, 48, 51, 52],

**Table 2** Types of infections, microorganisms, and antimicrobial agents in OPAT

Categories	Factors <sup>a</sup>	No. of studies (%) <sup>b</sup>	References
Main type of infections			
	Bone and joint	12 (52.2)	[35–37, 39, 41, 44, 46–48, 50, 51, 54]
	Skin and soft tissue	10 (43.5)	[34–37, 41, 46–49, 53]
	Respiratory tract	9 (39.1)	[35, 40, 41, 45–47, 49, 50, 51]
	Head and neck	6 (26.1)	[32, 33, 35, 41, 47, 51]
	Urinary tract	6 (26.1)	[40, 41, 45–47, 50]
	Endocarditis	5 (21.7)	[41–43, 47, 50]
	Bloodstream	3 (13.0)	[40, 41, 50]
	Diabetic foot	1 (4.3)	[52]
	HAI	1 (4.3)	[37]
Microorganism			
	<i>Pseudomonas aeruginosa</i>	5 (21.7)	[33, 41, 44, 51, 52]
	<i>Enterobacterales</i>	3 (13.0)	[40, 41, 52]
	<i>Staphylococcus</i> spp.	3 (13.0)	[36, 52, 53]
	<i>Streptococcus</i> spp.	2 (8.7)	[42, 53]
	<i>Acinetobacter baumannii</i>	1 (4.3)	[44]
	<i>Klebsiella pneumoniae</i>	1 (4.3)	[32]
	Microorganism with antimicrobial resistance	8 (34.8)	[34, 36, 39, 41, 43, 44, 51, 53]
	Not reported	10 (43.5)	[35, 37, 38, 45–50, 54]
Antimicrobial agent			
Beta-lactams			
	Ceftriaxone	12 (52.2)	[35, 38, 40, 42, 45–50, 53, 54]
	Ceftazidime	6 (26.1)	[33, 41, 45–47, 50]
	Piperacillin/tazobactam	5 (21.7)	[40, 41, 47, 50, 52]
	Meropenem	4 (17.4)	[40, 41, 47, 50]
	Cefepime	3 (13.0)	[41, 45, 50]
	Ceftolozane/tazobactam	2 (8.7)	[41, 51]
	Cefuroxime	2 (8.7)	[38, 45]
	Ertapenem	2 (8.7)	[40, 50]
	Cefiderocol	1 (4.3)	[32]
Glycopeptides	Teicoplanin	11 (47.8)	[34, 35, 39, 40, 42, 47–50, 53, 54]
Lipopeptides	Daptomycin	4 (17.4)	[34, 36, 40, 50]
Aminoglycosides	Gentamicin	3 (13.0)	[42, 50, 54]

HAI healthcare-associated infections, OPAT outpatient parenteral antimicrobial therapy

<sup>a</sup>Factors are not mutually exclusive

<sup>b</sup>Percentages are shares of the 23 included studies

**Table 3** Outcomes related to OPAT

Outcomes categories	Factors <sup>a</sup>	No. of studies (%) <sup>b</sup>	References
Clinical	Cure/clinical cure	13 (56.5)	[33, 39, 41, 42, 46–50, 52–54]
	Improvement/clinical improvement	11 (47.8)	[32, 33, 35, 39, 41, 43, 47–49, 52, 54]
	Relapse/re-admission	6 (26.1)	[34, 40, 41, 50, 53, 54]
	Failure	6 (26.1)	[35, 39, 41, 48, 52]
Safety	Adverse events	7 (30.4)	[36, 40, 41, 47, 48, 50]
	Reported	4 (17.4)	[32, 33, 39, 42]
	Reported as absent	12 (52.2)	[34, 35, 37, 38, 43–46, 49, 52–54]
	Not reported		
Pharmacological	PK/PD evaluation	1 (4.3)	[32]
Patient-reported	Belief, satisfaction	3 (13.0)	[46, 47, 54]
	Adherence, compliance	2 (8.7)	[39, 42]
Organizational	Hospital beds saved	3 (13.0)	[34, 37, 53]
	OPAT consumption	2 (8.7)	[38, 45]
	Protocols for OPAT	1 (4.3)	[34]
	OPAT integrated with antimicrobial stewardship	1 (4.3)	[40]
Economic	Impact on hospital	2 (8.7)	[34, 50]
	Impact for National System	2 (8.7)	[36, 37]
	Impact on personnel costs	1 (4.3)	[48]
	Injectable costs	1 (4.3)	[45]

OPAT outpatient parenteral antimicrobial therapy, PD pharmacodynamics, PK pharmacokinetic, PREM patient-reported experience measures, PROM patient-reported outcome measures

<sup>a</sup>Factors are not mutually exclusive

<sup>b</sup>Percentages are shares of the 23 included studies

with rates ranging between 0% [39] to 42.9% [41].

### **Safety Outcomes**

Adverse event (AE) reporting was inconsistent across studies, with almost half ( $n=12$ , 52.2%) providing no information on AEs. Seven studies (30.4%) [36, 40, 41, 47, 48, 50, 51] reported AEs, which were generally mild to moderate, particularly related to the device used for the administrations (e.g., catheter complications such as thrombosis), and drug reactions (e.g., rash or biochemical abnormalities). Frequencies of overall AEs varied from 0%, reported in four (17.4%) studies [32, 33, 39, 42] to 29% [41].

### **Pharmacological Outcomes**

A single study [32] evaluated pharmacokinetic/pharmacodynamic parameters in OPAT using continuous infusion via elastomeric pump with therapeutic drug monitoring, showing sustained cefiderocol exposures consistent with aggressive beta-lactam targets. The findings support the feasibility of pharmacokinetic/pharmacodynamic-guided continuous infusion strategies in outpatient settings, although evidence is limited to case-level data.

### **Patient-Reported**

Three studies reported a strong willingness among Italian patients to participate in OPAT; both also documented high satisfaction among patients and treating physicians [46, 47, 54]. Adherence and acceptability were high. Specifically, one outpatient teicoplanin cohort reported only three missed administrations out of 383 (0.78%) [39], while, similarly, high patient compliance was noted in a series of infective endocarditis [42].

### **Organizational Outcomes**

At the prescribing level, outpatient use of injectable cephalosporins between 1993 and 2002 averaged 0.6 DDD/1000 inhabitants/day,

peaked at 0.8 DDD/1000 inhabitants/day during 1996–2000, and subsequently declined [45]. In parallel, OPAT consumption was estimated at 0.7 DDD/1000 inhabitants/day, with the Italian share significantly higher than the European average [38]. At the system level, a scenario analysis of early discharge in infectious-disease departments estimated 16,393–38,990 inpatient days potentially avoided annually, corresponding to 57–135 hospital beds [37]; moreover, in a single-center cellulitis series, OPAT was associated with 2186 bed-days saved over 10 years [53]. Finally, one study reported that protocols explicitly including OPAT were available in 7.6% of Italian hospitals [34].

### **Economic Outcomes**

Economic evaluations of OPAT were infrequent and methodologically heterogeneous, with varying perspectives and inclusion of direct medical costs and system-level effects. Per-patient savings estimates likewise differed by context and approach: approximately €1150 in early conservative analyses [36]; €2430–€2642 in modeled estimates for methicillin-resistant *Staphylococcus aureus* complicated skin and soft tissue infection [34]; and about €5600 in contemporary real-world cohorts receiving prolonged intravenous therapy via elastomeric pumps [51]. At the utilization level, European surveillance ranked Italy among the highest consumers of outpatient parenteral cephalosporins, predominantly ceftriaxone, with related budgetary implications [38].

## **DISCUSSION**

### **Summary of Main Findings**

This scoping review identified 23 Italian studies on OPAT published between 2000 and 2025, with an increase in publications after 2021. Most studies were observational and single-center, with only one interventional study. OPAT delivery models were diverse, occurring mainly at home or in specialized infusion

centers, and less frequently in outpatient clinics. The studies primarily addressed infections such as bone and joint, skin and soft tissue, and respiratory tract infections, while endocarditis, bloodstream infections, and diabetic foot infections were less frequently reported. Beta-lactam agents, particularly ceftriaxone, were the main antimicrobial regimens used, with teicoplanin as the principal glycopeptide. Recent studies reported the use of newer agents such as ceftolozane/tazobactam. Intravenous administration was common, often employing elastomeric pumps and various vascular access devices. Clinical outcomes were generally favorable, with over 90% of patients achieving cure or improvement, low relapse and re-admission rates, and few adverse events, although safety data reporting was inconsistent. Limited patient-reported outcomes indicated high satisfaction, while few studies assessed organizational and economic impacts, suggesting potential cost reductions. Taken together, the findings suggest that OPAT can be delivered with favorable outcomes in selected Italian settings, but they also underscore the need for improved standardized reporting.

### Clinical Interpretation and Antimicrobial Use

From a clinical perspective, Italian OPAT has mainly been used for infections requiring prolonged parenteral therapy, such as osteomyelitis, prosthetic joint infection, diabetic foot infection, complicated skin and soft-tissue infection, and infective endocarditis. These conditions are usually managed as a continuation of inpatient treatment rather than as primary therapy, consistent with international experience [1, 5, 8]. In this context, the predominance of ceftriaxone and other third-generation cephalosporins in Italian OPAT cohorts likely reflects their once-daily dosing and broad spectrum, which could be convenient in ambulatory care. However, this must be balanced against national and European concerns regarding cephalosporin overuse and the selection of extended-spectrum  $\beta$ -lactamase producers, as well as ecological data showing

a relatively high proportion of parenteral cephalosporins in outpatient consumption in Italy compared with other European countries [6, 38]. The Italian OPAT evidence also documents the early use of glycopeptides and lipopeptides, particularly teicoplanin and daptomycin, for methicillin-resistant staphylococcal osteomyelitis and other serious Gram-positive infections, consistent with global OPAT practice in which once-daily or long-acting agents facilitate management of resistant pathogens outside hospital, albeit often at higher drug acquisition costs [5, 8]. More recently, Italian experiences have extended OPAT to last-resort  $\beta$ -lactams such as cefiderocol and ceftolozane/tazobactam, delivered by continuous infusion in elastomeric pumps, sometimes supported by therapeutic drug monitoring, to treat difficult-to-treat resistant *Pseudomonas aeruginosa* and carbapenemase-producing Enterobacterales [32, 41, 51]. In parallel, newer agents such as ceftobiprole have emerged as potentially suitable for OPAT because of their physicochemical stability, compatibility with elastomeric devices, feasibility of continuous infusion and encouraging data on clinical cure [55–57]. Together, these developments may support a broader role for continuous or extended infusion of time-dependent  $\beta$ -lactams in OPAT, which, provided that stability and delivery accuracy are ensured, may optimise pharmacokinetic/pharmacodynamic exposure, simplify administration schedules, and reduce healthcare resource utilization [13, 58, 59].

Across these heterogeneous Italian cohorts, clinical cure or improvement was frequently reported in more than 80–90% of patients (e.g., [42]), with low levels of reported mortality directly attributable to infection or treatment failure (e.g., [47]), and apparently infrequent unplanned hospital readmissions after completion of OPAT (e.g., [34]). However, the absence of control groups, variable outcome definitions, and limited long-term follow-up mean that these favorable clinical outcomes should be interpreted with caution.

## Patient-Related Outcomes

From the patient's perspective, outcomes were explored in only a minority of Italian OPAT studies. When assessed, satisfaction with OPAT was generally high, and patients often expressed a clear preference for receiving treatment at home rather than in hospital (e.g., [54]). These findings are consistent with international evidence suggesting that OPAT may support quality of life by allowing patients to remain in their usual environment, maintain daily activities and family roles, and potentially reduce exposure to healthcare-associated infections, with perceived benefits for both physical and emotional well-being [60–62]. The levels of adherence and compliance appeared high, with very few missed doses recorded in the cohorts. However, these levels were rarely quantified [39, 42]. A recent survey outside Italy found that nearly 90% of patients self-reported full adherence during OPAT, with non-adherence associated with younger age, lower income and time constraints, while less frequent dosing schedules and family support favored adherence [63]. These data highlight the importance of considering both individual and contextual factors when evaluating adherence. Furthermore, some missed administrations may reflect system-level issues (such as scheduling, coordination, or logistics) rather than patient behavior, a distinction that warrants explicit assessment in future studies.

## Organizational and Economic Outcomes

Across the Italian OPAT evidence, only few studies provide quantitative estimates of resource use or costs, generally considered as secondary or modeled outcomes rather than primary endpoints (e.g., [36]). Scenario analyses suggest that reductions in hospital bed-days and net cost savings for the Italian National Health Service may be achievable, primarily through early discharge of patients with acute bacterial skin and skin-structure infections and osteomyelitis [37]. In addition, OPAT was associated with lower total therapy costs

compared with continued inpatient care in a large multinational study [36].

When these findings are interpreted considering ecological data on antimicrobial use, a more complex picture emerges. Injectable cephalosporins are frequently prescribed in community settings in Italy, and OPAT consumption of parenteral cephalosporins exceeds the European average [38, 45]. This pattern suggests that potential organizational and economic gains related to reduced hospitalization may coexist with prescribing profiles that are not fully aligned with antimicrobial stewardship goals, particularly regarding extensive use of broad-spectrum cephalosporins [38]. From an economic perspective, such prescribing practices may entail downstream costs linked to resistance selection and *Clostridioides difficile* infection that are not captured in the available Italian OPAT analyses, in line with other studies outside Italy [64, 65].

International evidence indicates that OPAT can be cost-saving or at least cost-neutral, but also shows that the magnitude and direction of economic effects depend strongly on programme design, case mix, local bed pressures and the extent to which non-billable activities, such as coordination, patient education, line care, and follow-up are accounted for [8, 9, 66]. In particular, studies from other settings suggest that dedicated OPAT teams and clear governance structures may optimise both resource use and clinical outcomes, whereas fragmented models risk shifting workload to professionals without adequate recognition or funding [66, 67].

Overall, the available Italian data are sparse and heterogeneous: they may support the hypothesis that OPAT can contribute to bed-day reduction and cost containment, but they do not yet clarify under which organizational conditions, for which patient subgroups and with what balance between direct savings and indirect costs these potential benefits are realized, underscoring the need for prospectively planned health-economic evaluations.

## Italy-Specific Contextual Factors and International Comparisons

Italian OPAT evidence in the included studies mainly reflects locally developed care pathways, which are largely hospital-based and in some cases extended to community and primary care settings. Nurses are consistently involved in vascular access management, antimicrobial administration, and monitoring, and some pathways explicitly include general practitioners and/or community services to support follow-up and continuity of care. However, reporting on governance arrangements, formal protocols, and regional or national regulatory frameworks is limited, and the heterogeneity of settings and study designs prevents robust conclusions about OPAT organization at the national level.

Historical participation in the International OPAT Registry [47], together with the subsequent description of single-center and multicenter experiences (e.g., [40, 51]) suggests a progressive but uneven development of OPAT activities over time. In one international survey, only a minority of Italian hospitals reported having protocols that explicitly included OPAT [34]. Available evidence suggests that OPAT-specific pathways, stewardship-linked governance, and routine outcome monitoring exist in some settings but are not consistently documented or standardized, limiting precise national inferences. Consistent with international findings, more formalized, multidisciplinary OPAT services appear to improve patient safety and cost-effectiveness, supporting the case for structured models [9, 18, 68].

At the same time, Italy faces a high burden of antimicrobial resistance and healthcare-associated infections, particularly in hospitals and long-term care facilities [6, 7]. These pressures, along with structural constraints on hospital bed capacity that became especially evident during the COVID-19 pandemic [4], may provide a strong macro-level rationale for developing safe and effective OPAT pathways as part of broader strategies for hospital decongestion and antimicrobial stewardship [1, 8, 66].

## Challenges and Future Directions

Building on the gaps identified in this scoping review, several priorities for future work on OPAT in Italy can be outlined.

First, prospective, multicenter studies with clearly defined comparison groups and core outcome sets are needed to move beyond single-center observational descriptions and provide more robust evidence on effectiveness, safety, and equity of access.

Second, although the included studies consistently acknowledge the involvement of multiple professionals, particularly nurses, general practitioners, infectious diseases specialists and, less frequently, pharmacists, their roles are only briefly outlined and are rarely examined in relation to competencies, workload or specific contributions to patient and system outcomes. More detailed description and evaluation of these roles could clarify how OPAT interacts with evolving community and district nursing models and with antimicrobial stewardship activities, drawing on international experience with dedicated OPAT teams and nurse- or pharmacist-led components [9, 66, 67, 69].

Third, none of the included studies reported the use of structured risk-stratification tools, formal OPAT eligibility scores or standardized escalation pathways, so the criteria by which patients are selected for OPAT, monitored in the community and readmitted when necessary remain largely implicit in published reports. Although local protocols may exist but are not fully described, future work should adapt and evaluate risk-stratification, monitoring and intravenous-to-oral switch criteria in line with international guidance [9, 22] and with evidence that inadequate early risk assessment predicts adverse outcomes and re-admission [70].

Fourth, organizational and economic aspects are only partially addressed in the current Italian evidence base. Although some studies and scenario analyses suggest that OPAT may reduce bed occupancy and generate cost savings for the health system, these evaluations are few, methodologically heterogeneous, and rarely consider the full range of hospital and

community resources involved, including non-billable coordination and follow-up activities. Prospective Italian studies incorporating formal health-economic analyses, integrated with clinical, microbiological, and patient-reported outcomes, would help to identify the organizational conditions under which OPAT offers the greatest benefit and how it can be sustainably scaled within a regionalized National Health Service.

Finally, formal national OPAT-specific guidelines or standardized protocols are not yet described, and implementation appears to rely largely on regional and local initiatives. The development of nationally endorsed OPAT-specific frameworks and guidance, adaptable to regional organization and explicitly incorporating standardized patient-reported outcome measures, patient-reported experience measures and stewardship and economic indicators, could support more consistent practice, clarify roles and governance and facilitate systematic monitoring and evaluation.

### Limitations

This review has several limitations. First, the search strategy prioritized records explicitly labeled “OPAT”; relevant Italian experiences described under alternative terms (e.g., injectable therapy) may have been missed, potentially underestimating the published studies.

Second, possible duplication arising from multiple topic-related papers by the same author was not addressed; these were counted as independent studies, potentially leading to dataset overlap and biased frequency estimates.

Finally, according to the nature of the scoping review, study quality was not appraised, and no formal risk-of-bias assessment was undertaken, limiting insight into the robustness of the findings.

## CONCLUSIONS

This scoping review indicates that OPAT in Italy is feasible and appears to be increasingly used

in selected settings yet remains heterogeneous across regions and service configurations. Delivery occurred predominantly at home and in infusion facilities, with bone and joint, respiratory, skin and soft-tissue, and urinary infections most frequently treated, and beta-lactams as the most used agents. Reported clinical outcomes are generally favorable, with low rates of relapse and readmission, and adverse events that were predominantly device-related and uncommon. Roles and responsibilities were variably reported, but nursing activity was consistently documented for drug administration and vascular-access care, and general practitioners are described as contributing to community monitoring and continuity of care in selected pathways. Implementation was locally adapted in coordination with infectious-disease services and community providers, within the constraints of regional governance and prescribing rules. The limited diffusion of stewardship-linked OPAT pathways and multidisciplinary teams may be related to organizational fragmentation and to the lack, in the literature identified by this review, of OPAT-specific national guidance, although the available evidence does not allow firm system-level conclusions. Economic evaluations remain scarce but suggest potential savings primarily driven by avoided inpatient days, while results are likely context dependent.

Within the Italian health system, scaling OPAT may be supported by leveraging community and primary care services, formalizing multidisciplinary teams led by infectious-disease specialists and underpinned by antimicrobial stewardship programs, enhancing the training and deployment of OPAT-competent nurses, and systematically engaging caregivers to sustain safety, adherence, and equitable access. To translate feasibility into reliable, scalable practice, priorities include nationally endorsed guidance, standardized definitions and core outcome sets with standardized outcome capture within a registry framework, and investment in workforce capacity. Comparative evaluations of care models and administration strategies, alongside rigorous economic assessments, are needed to inform equitable

scale-up aligned with national strategies on HAIs and antimicrobial resistance.

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**Data Availability.** All data generated or analyzed during this study are included in this published article/as supplementary information files.

#### **Declarations**

**Conflict of Interest.** Chiara Moreal, Simone Giuliano, Francesca Prativiera, Massimo Fantoni, Sergio Mezzadri, Valentina Menozzi, Meri Marin, Raul Cetatean, Elena Sora, Elena Rosselli Del Turco, Fabio Tumietto, Cristina Moracas, Alfredo Guarino, Riccardo Vecchio, Anna Odone, Vilma Urbančič, Alvisa Palese and Carlo Tascini declared no conflict of interests.

**Ethical Approval.** This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

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