

Formulary Management

Gene Therapy (1802)

Source: Council on Pharmacy Management

To assert that health-system decisions on the selection, use, and management of gene therapy agents should be managed as part of the medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; further,

To advocate that gene therapy be documented in the permanent patient health record; further,

To advocate that documentation of gene therapy in the permanent patient health record accommodate documentation by all healthcare team members, including pharmacists.

This policy supersedes ASHP policy 0103.

Medication Formulary System Management (1805)

Source: Council on Pharmacy Management

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; and (3) should not be based solely on economic factors.

This policy supersedes ASHP policy 0102.

Medical Devices (1820)

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,

To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

This policy supersedes ASHP policy 9106.

Pharmacogenomics (1104)

Source: Council on Therapeutics

To advocate that pharmacists take a leadership role in the therapeutic applications of pharmacogenomics, which is essential to individualized drug therapy; further,

To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To encourage pharmacist education on the use of pharmacogenomics and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.

This policy was reviewed in 2015 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Generic Substitution of Narrow Therapeutic Index Drugs (0817)

Source: Council on Therapeutics

To support the current processes used by the Food and Drug Administration (FDA) to determine bioequivalence of generic drug products, including those with a narrow therapeutic index, and to recognize the authority of the FDA to decide if additional studies are necessary to determine equivalence; further,

To oppose a blanket restriction on generic substitution for any medication or medication class without evidence from well-designed, independent studies that demonstrate inferior efficacy or safety of the generic drug product.

This policy was reviewed in 2012 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Expression of Therapeutic Purpose of Prescribing (0305)

Source: Council on Professional Affairs

To advocate that the prescriber provide or pharmacists have immediate access to the intended therapeutic purpose of prescribed medications in order to ensure safe and effective medication use.

This policy was reviewed in 2017 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Standardization of Drug Medication Formulary Systems (9601)

Source: Council on Administrative Affairs

To support the concept of a standardized medication formulary system among components of integrated health systems when standardization leads to improved patient outcomes; further,

To include in the formulary-standardization process the direct involvement of the health system's physicians, pharmacists, and other appropriate health care professionals.

This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Therapeutic Interchange (8708)

Source: Council on Legal and Public Affairs

To support the concept of therapeutic interchange of various drug products by pharmacists under arrangements where pharmacists and authorized prescribers interrelate on the behalf of patient care.

This policy was reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

ASHP Policy Positions 2009–2018 (with Rationales): Formulary Management (Medication-Use Policy Development)

1802

Gene Therapy

Source: Council on Pharmacy Management

To assert that health-system decisions on the selection, use, and management of gene therapy agents should be managed as part of the medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; further,

To advocate that gene therapy be documented in the permanent patient health record; further,

To advocate that documentation of gene therapy in the permanent patient health record accommodate documentation by all healthcare team members, including pharmacists.

This policy supersedes ASHP policy 0103.

Rationale

The first biologics license agreement for a gene therapy product was submitted to the Food and Drug Administration in May 2017. Gene therapy is an emerging area of medicine, and pharmacists should take a leadership role in managing these therapies and associated devices under the medication formulary systems in their institutions.

As described in more detail in the [ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System](#), a fundamental characteristic of the formulary system is that all decisions are made based on factors that result in optimal patient care, include the involvement of appropriate healthcare professionals, and are not based solely on economic factors. It is important that gene therapy be documented in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and to validate the impact of therapies on patient outcomes and that all healthcare providers involved in providing gene therapy, including pharmacists, be able to document the patient care provided.

1805

Medication Formulary System Management

Source: Council on Pharmacy Management

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; (2) must include the active and direct involvement of physicians, pharmacists, and

other appropriate healthcare professionals; and (3) should not be based solely on economic factors.

This policy supersedes ASHP policy 0102.

Rationale

A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for healthcare organizations to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and cost-effective medication therapy. The formulary system is the ongoing process through which a healthcare organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

As described in more detail in the [ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System](#), a fundamental characteristic of the formulary system is that all decisions are made based on factors that result in optimal patient care, include the involvement of appropriate healthcare professionals, and are not based solely on economic factors.

1820

Medical Devices

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,

To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

This policy supersedes ASHP policy 9106.

Rationale

The lines between devices, drugs, and technology are blurring as new and innovative technologies combine drugs and devices. Because drugs and medical devices undergo different approval processes, it is important that compatibility between the intended use of any device and the drugs to be used with that device be ensured during the approval process so that unintended and possibly detrimental consequences do not occur. In addition, clinicians require

information about the intended use of devices in all phases of the medication-use process in order to make the best-informed decisions about patient care.

1104**PHARMACOGENOMICS**

Source: Council on Therapeutics

To advocate that pharmacists take a leadership role in the therapeutic applications of pharmacogenomics, which is essential to individualized drug therapy; further,

To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To encourage pharmacist education on the use of pharmacogenomics and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.

This policy supersedes ASHP policy 0016.

Rationale

The Council reviewed ASHP policy 0016, Pharmacogenomics, as part of a larger discussion on marketing and clinical application of genetic tests available to consumers. The Council voted and the Board and House agreed to amend this policy to more clearly define the role of pharmacists in pharmacogenomic testing.