Policies Repository

AmeriHealth.

Policy Title	Oral Chemotherapy Agents
Policy Number	FS.CLIN.11

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

IMATINIB MESYLATE (GLEEVEC®)
Imatinib mesylate (Gleevec®) is indicated for the treatment of all of the following:

- Acute lymphoblastic leukemia (ALL)
- Aggressive systemic mastocytosis (ASM)
- Dermatofibrosarcoma protuberans (DFSP)
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)
- Kit-positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST)
- Myelodysplastic/myeloproliferative diseases (MDS/MPD)
- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in blast crisis phase, accelerated phase, or chronic phase after failure of interferon-alpha therapy

GEFITINIB (IRESSA®)
Gefitinib (Iressa®) is indicated as monotherapy for the treatment of individuals with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure with both platinum-based or docetaxel chemotherapies. The effectiveness of gefitinib (Iressa®) is based on objective response rates. There are no controlled trials demonstrating a clinical benefit such as improved disease-related symptoms or increased survival. Results from two large controlled randomized trials in first-line treatment of NSCLC showed no benefit from adding gefitinib (Iressa®) to doublet, platinum-based chemotherapy. Therefore, gefitinib (Iressa®) is not indicated for use in this setting.
The US Food and Drug Administration (FDA) has limited the use of gefitinib (Iressa®) to individuals who have previously benefited from therapy or to those who are involved in a clinical trial that has been approved by the Institutional Review Board prior to June 17, 2005. No individuals may initiate therapy after September 15, 2005. Gefitinib (Iressa®) will be administered to qualified individuals through the Iressa Access Program.

SORAFENIB (NEXAVAR®)
Sorafenib (Nexavar®) is indicated for the treatment of advanced renal cell carcinoma and advanced

unresectable hepatocellular carcinoma.

LENALIDOMIDE (REVLIMID®)
Lenalidomide (Revlimid®) is indicated for the treatment of individuals who have transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes that are associated with a deletion 5q cytogenetic abnormality, with or without additional cytogenetic abnormalities. Lenalidomide (Revlimid®) in combination with dexamethasone is indicated for the treatment of multiple myeloma in individuals who have received at least one prior therapy.

DASATINIB (SPRYCEL®)
Dasatinib (Sprycel®) is indicated for the treatment of adults with all phases of chronic myeloid leukemia who have demonstrated resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec®). Dasatinib (Sprycel®) is also indicated for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) who have demonstrated resistance or intolerance to prior therapy.

SUNITINIB MALATE (SUTENT®)
Sunitinib malate (Sutent®) is indicated for the treatment of the following conditions:

- GIST after trial and failure of or intolerance to imatinib mesylate (Gleevec®)
- Advanced renal cell carcinoma (RCC)

ERLOTINIB (TARCEVA®)
Erlotinib (Tarceva®) is indicated for the treatment of individuals who have locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

THALIDOMIDE (THALOMID®)
Thalidomide (Thalomid®) is indicated for the following:

- The acute treatment of and maintenance therapy for erythema nodosum leprosum (ENL)
- The acute treatment of moderate-to-severe neuritis (not as monotherapy)
- First-line therapy for multiple myeloma
- Use in neoplastic disorders that are not responsive to conventional treatment

VORINOSTAT (ZOLINZA®)
Vorinostat (Zolinza®) is a histone deacetylase (HDAC) inhibitor indicated for the treatment of individuals with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent, or recurrent disease on or following two systemic therapies.

LAPATINIB (TYKERB®)
Lapatinib (Tykerb®) is indicated for use in combination with capecitabine (Xeloda®) for the treatment of individuals with advanced or metastatic breast cancer whose tumors overexpress the HER2 protein and who have received prior therapy with an anthracycline, a taxane, and trastuzumab (Herceptin®).

NILOTINIB (TASIGNA®)
Nilotinib (Tasigna®) is indicated for the treatment of chronic-phase and accelerated-phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML) in adult patients resistant to or intolerant to prior therapy that included imatinib (Gleevec®).

Topotecan capsule (Hycamtin®)
Topotecan capsule (Hycamtin®)is indicated for the treatment of relapsed small cell lung cancer in patients with a prior complete or partial response and who are at least 45 days from the end of first-line chemotherapy.

PRIOR AUTHORIZATION The use of any of the following drugs requires prior authorization (ie, clinical pharmacy and/or Medical Director review):

- Imatinib mesylate (Gleevec®)
- Gefitinib (Iressa®)
- Sorafenib (Nexavar®)
- Lenalidomide (Revlimid®)
- Dasatinib (Sprycel®)
- Sunitinib malate (Sutent®)
- Erlotinib (Tarceva®)
- Thalidomide (Thalomid®)
- Vorinostat (Zolinza®)
- Lapatinib (Tykerb®)
- Topotecan capsule (Hycamtin®)

Policy Description

IMATINIB MESYLATE (GLEEVEC®)
Imatinib mesylate (Gleevec®) is the first signal transduction inhibitor to be approved by the US Food and Drug Administration (FDA). These drugs are designed to prevent and stop the growth of cancer cells. Imatinib mesylate (Gleevec®) directly blocks BCR-ABL, the protein necessary for leukemia cells to survive. Imatinib mesylate (Gleevec®) also targets the activity of certain enzymes called tyrosine kinases, which play an important role within certain cancer cells. The activity of one of these tyrosine kinases, known as a stem cell factor receptor (c-Kit), is thought to drive the growth and division of most gastrointestinal stromal tumors (GISTs).

GEFITINIB (IRESSA®)
Gefitinib (Iressa®) is known as a transduction inhibitor because it blocks (inhibits) signals within a cancer cell to prevent a series of chemical reactions that cause the cell to grow and divide. Epidermal growth factor receptors (EGFRs) are found on the surface of many types of cancer cells. These receptors allow the epidermal growth factor (EGF), a particular protein present in the body, to attach to them. When EGF attaches to the receptor, it causes a chemical called tyrosine kinase to trigger chemical processes inside the cell that makes it grow and divide. When gefitinib (Iressa®) attaches itself to the EGF receptor inside the cell, it blocks the activation of tyrosine kinase and switches off the EGFR signals. Therefore, gefitinib (Iressa®) has the potential to stop cancer cells from growing. It works in a different way to supplement both chemotherapy and hormonal therapy.

SORAFENIB (NEXAVAR®)
Sorafenib (Nexavar®) is a multikinase inhibitor that decreases tumor cell proliferation. The mechanism of action of sorafenib (Nexavar®) is not well understood, but it is believed to inhibit tumor growth in murine renal cell carcinoma and several other human tumor xenograft models. Sorafenib (Nexavar®) has also been shown to interact with multiple intracellular (CRAF, BRAF, and mutant BRAF) and cell surface kinases (KIT, FMS-like tyrosine kinase-3 [FLT-3], vascular endothelial growth factor receptors [VEGFR-3], and platelet-derived growth factor receptors [PDGFRß]), several of which are thought to be involved in angiogenesis.

LENALIDOMIDE (REVLIMID®)
Lenalidomide (Revlimid®) is a thalidomide analogue. The mechanism of action of lenalidomide (Revlimid®) is not well understood. It possesses immunomodulatory and antiangiogenic properties, inhibits the secretion of proinflammatory cytokines, and increases the secretion of anti-inflammatory cytokines from peripheral blood mononuclear cells. Lenalidomide (Revlimid®) inhibits cell proliferation with varying effectiveness in some, but not all, cell lines. Of the cell lines tested, lenalidomide (Revlimid®) was effective in inhibiting the growth of Namalwa cells (a line of human B-lymphocytes with a deletion of one chromosome 5) but was much less effective in the inhibition of KG-1 cells (human myeloblastic cell lines with a deletion of one chromosome 5) and other cell lines without a chromosome 5 deletion. Lenalidomide (Revlimid®) inhibited the expression of cyclooxygenase-2 (COX-2) but not cyclooxygenase-1 (COX-1) in vitro.

DASATINIB (SPRYCEL®)

Dasatinib (Sprycel®) is a multityrosine kinase inhibitor that limits the activity of BCR-ABL, SRC family, c-Kit, EPHA2, and PDGFRß tyrosine kinases. This results in an inhibition of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) cell lines that overexpress BCR-ABL. Dasatinib (Sprycel®) has also been shown to be effective for individuals who have demonstrated resistance or intolerance to imatinib mesylate (Gleevec®).

SUNITINIB MALATE (SUTENT®)
Sunitinib malate (Sutent®) is a multikinase inhibitor that targets several receptor tyrosine kinases (RTKs), some of which are implicated in tumor growth, pathologic angiogenesis, and/or a metastatic progression of cancer. The mechanism of action of sunitinib malate (Sutent®) is not well understood. It is believed that sunitinib malate (Sutent®) inhibits platelet-derived growth factor receptors (PGFRa and PDGFRß), vascular endothelial growth factor receptors (VEGR1, VEGFR2, and VEGFR3), c-Kit, FLT3, colony-stimulating factor 1 receptor (CSF-1R), and the glial cell line-derived neutrophic factor receptor (RET). Several of these kinases are thought to be involved in angiogenesis.

ERLOTINIB (TARCEVA®)
Erlotinib (Tarceva®) is described as a human epidermal growth factor receptor type 1 (HER1)/EGFR tyrosine kinase inhibitor. Its mechanism of antitumor action is not fully understood. It inhibits the phosphorylation of tyrosine kinase associated with EGFR. The specificity of tyrosine kinase receptor inhibition has not been defined. EGFR is expressed on the cell surfaces of normal cells and cancer cells. Two multicenter, placebo-controlled, randomized Phase III trials were conducted in first-line individuals who had locally advanced or metastatic non-small cell lung cancer (NSCLC), and the results showed no clinical benefit with the concurrent administration of erlotinib (Tarceva®). Erlotinib (Tarceva®) with platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) is not recommended for use in this setting.

THALIDOMIDE (THALOMID®)
Thalidomide (Thalomid®) is a derivative of glutamic acid and glutethimide. The mechanism of action of thalidomide (Thalomid®) is not well understood. It is believed, however, that it suppresses excessive tumor necrosis factor alpha (TNF-a) production, and it also disturbs the adhesion of leukocytes on the cell surface.

VORINOSTAT (ZOLINZA®)
Vorinostat (Zolinza®) inhibits the enzymatic activity of histone deacetylases (HDACs) Class I (ie, HDAC1, HDAC2, and HDAC3) and Class II (ie, HDAC6) at nanomolar concentrations (inhibitory concentration [IC50] less than 86 nM). In some cancer cells, there is an overexpression of HDACs or an aberrant recruitment of HDACs to oncogenic transcription factors causing hypoacetylation of core nucleosomal histones. Hypoacetylation of histones is associated with a condensed chromatin structure and repression of gene transcription. Inhibition of HDAC activity allows for the accumulation of acetyl groups on the histone lysine residues, resulting in an open chromatin structure and transcription activation. In vitro, vorinostat (Zolinza®) causes the accumulation of acetylated histones and induces cell cycle arrest and/or apoptosis of some transformed cells. The mechanism of the antineoplastic effect of vorinostat (Zolinza®) is not fully understood.

LAPATINIB (TYKERB®)
Lapatinib (Tykerb®) is an inhibitor of the EGFR (Epidermal growth factor receptor; also called HER1 or ErbB1) and HER2 receptor tyrosine kinases, thereby inhibiting ErbB-driven tumor cell growth.

NILOTINIB (TASIGNA®)
Nilotinib (Tasigna®) is a selective tyrosine kinase inhibitor which binds to and stabilizes the inactive conformation of the kinase domain of the Abl protein. Bcr-Abl is the oncogenic tyrosine kinase expressed by Philadelphia chromosome-positive (Ph+) stem cells, directly involved in the pathogenesis of CML. Nilotinib inhibits the autophosphorylation of Bcr-Abl, PDGFR, and c-Kit, thereby reducing the tumor size.

Topotecan capsule (Hycamtin®)
Topotecan capsule (Hycamtin®) is a semi-synthetic derivative of camptothecin and is an anti-tumor drug. The anti-tumor activity of topotecan involves the inhibition of topoisomerase-I, an enzyme

intimately involved in DNA replication as it relieves the torsional strain introduced ahead of the moving replication fork. Topotecan inhibits topoisomerase-I by stabilizing the covalent complex of enzyme and strand-cleaved DNA, which is an intermediate of the catalytic mechanism. The cellular sequel of inhibition of topoisomerase-I by topotecan is the induction of protein-associated DNA single-strand breaks. The cytotoxicity of topotecan is thought to be due to double strand DNA damage produced during DNA synthesis, when replication enzymes interact with the ternary complex formed by topotecan, topoisomerase I, and DNA. Mammalian cells cannot efficiently repair these double strand breaks.

Policy Guideline Inclusion

Imatinib mesylate (Gleevec®) is approved when **one** of the following inclusion criteria is met:

- Documentation of a diagnosis of acute lymphoblastic leukemia (ALL)
- Documentation of a diagnosis of aggressive systemic mastocytosis (ASM)
- Documentation of a diagnosis of chronic myeloid leukemia (CML)
- Documentation of a diagnosis of dermatofibrosarcoma protuberans (DFSP)
- Documentation of a diagnosis of gastrointestinal stromal tumors (GIST)
- Documentation of prevention for recurrence of gastrointestinal stromal tumor (GIST) after surgery to remove the tumor
- Documentation of a diagnosis of hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)
- Documentation of a diagnosis of myelodysplastic/myeloproliferative diseases (MDS/MPD)
- Documentation of a diagnosis of neoplastic disease with documentation of the failure of conventional therapy

Gefitinib (Iressa®) is approved when the following inclusion criterion is met:

- The individual was documented as previously benefiting from gefitinib (Iressa®) therapy before September 15, 2005 and has registered through the Iressa Access Program to continue therapy.

Sorafenib (Nexavar®) is approved when **one** of the following inclusion criteria is met:

- Documentation of a diagnosis of advanced renal cell carcinoma
- Documentation of a diagnosis of unresectable hepatocellular carcinoma

Lenalidomide (Revlimid®) is approved for individuals who are registered with the RevAssist(SM) Program when **one** of the following inclusion criteria is met:

- Documentation of a diagnosis of transfusion-dependent anemia, due to low- or intermediate-1-risk myelodysplastic syndromes that are associated with a deletion 5q cytogenetic abnormality, with or without additional cytogenetic abnormalities
- Documentation of a diagnosis of multiple myeloma in combination with dexamethasone for individuals who received at least one prior therapy (eg, stem cell transplantation, thalidomide, dexamethasone, mephalan, doxorubicin, vincristine, cyclophosphamide, carmustine, velcade)

Dasatinib (Sprycel®) is approved when **one** of the following inclusion criteria is met:

- Documentation of a diagnosis of CML in any phase (chronic, accelerated, myeloid, or lymphoid blast phase) with resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec®)
- Documentation of a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) with resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec®)

Sunitinib malate (Sutent®) is approved when **one** of the following inclusion criteria is met:

- Documentation of a diagnosis of gastrointestinal stromal tumors (GIST) after disease progression on imatinib mesylate (Gleevec®) or documented intolerance to imatinib mesylate (Gleevec®)
- Documentation of a diagnosis of advanced renal cell carcinoma (RCC)

Erlotinib (Tarceva®) is approved when **one** of the following inclusion criteria is met:

- Documentation of a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and documentation of at least one prior chemotherapy regimen that failed or is contraindicated
- Documentation of a diagnosis of pancreatic cancer in combination with gemcitabine (Gemzar®) as a first-line therapy

Thalidomide (Thalomid®) is approved when **one** of the following inclusion criteria is met:

- Documentation of acute treatment of cutaneous manifestations of moderate-to-severe erythema nodosum leprosum (ENL)
- Documentation of maintenance therapy for prevention and suppression of erythema nodosum leprosum (ENL) occurrence
- Documentation of first-line therapy for multiple myeloma
- Documentation of a diagnosis of neoplastic disease with documented failure of conventional therapy

Vorinostat (Zolinza®) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of cutaneous T-cell lymphoma (CTCL)
- Documentation of the trial and failure of, or contraindication to, at least two systemic therapies

Lapatinib (Tykerb®) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of advanced or metastatic breast cancer
- Documentation of a tumor with overexpression of HER2
- Documentation of concurrent treatment with capecitabine
- Documentation of prior therapy with all of the following:
    - An anthracycline
    - A taxane
    - Trastuzumab (Herceptin®)

Nilotinib (Tasigna®) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of chronic-phase or accelerated-phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML)
- Documentation of resistance to or intolerance to imatinib mesylate (Gleevec®)

Topotecan capsule (Hycamtin®) is approved when **all** of the following inclusion criteria are met:

- Documentation of diagnosis of small cell lung cancer

- Documentation of complete or partial response to one of the following first-line chemotherapy agents:
  - Cisplatin
  - Carboplatin
  - Etoposide
  - Irinotecan
  - Cyclophosphamide
  - Doxorubicin
  - Vincristine
  - Intravenous Topotecan
  - Ifosfamide
  - Paclitaxel
  - Docetaxel
  - Gemcitabine

Policy Guideline Exclusion

Imatinib mesylate (Gleevec®) is denied when **all** of the following exclusion criteria are present:

- No documentation of a diagnosis of acute lymphoblastic leukemia (ALL)
- No documentation of a diagnosis of aggressive systemic mastocytosis (ASM)
- No documentation of a diagnosis of chronic myeloid leukemia (CML)
- No documentation of a diagnosis of dermatofibrosarcoma protuberans (DFSP)
- No documentation of a diagnosis of gastrointestinal stromal tumors (GIST)
- No documentation of prevention for recurrence of gastrointestinal stromal tumor (GIST) after surgery to remove the tumor
- No documentation of a diagnosis of hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)
- No documentation of a diagnosis of myelodysplastic/myeloproliferative diseases (MDS/MPD)
- No documentation of a diagnosis of neoplastic disease with documentation of the failure of conventional therapy

Gefitinib (Iressa®) is denied when the following exclusion criterion is present:

- The individual started gefitinib (Iressa®) therapy after September 15, 2005.

CLINICAL TRIALS Gefitinib (Iressa®) used in a clinical trial is considered experimental/investigational and, therefore, not covered.

Sorafenib (Nexavar®) is denied when **all** of the following exclusion criteria are present:

- No documentation of a diagnosis of advanced renal cell carcinoma
- No documentation of a diagnosis of unresectable hepatocellular carcinoma

Lenalidomide (Revlimid®) is denied when **any** of the following exclusion criteria are present:

- The individual is not registered with the RevAssist(SM) Program.
- No documentation of a diagnosis of transfusion-dependent anemia, due to low- or intermediate-1-risk myelodysplastic syndromes that are associated with a deletion 5q cytogenetic abnormality, with or without additional cytogenetic abnormalities OR No documentation of a diagnosis of multiple myeloma in combination with dexamethasone for individuals who received at least one prior therapy (eg, stem cell transplantation, thalidomide, dexamethasone, mephalan, doxorubicin, vincristine, cyclophosphamide,

carmustine, velcade)

Dasatinib (Sprycel®) is denied when **all** of the following exclusion criteria are present:

- No documentation of a diagnosis of CML in any phase (chronic, accelerated, myeloid, or lymphoid blast phase) with resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec®)
- No documentation of a diagnosis of Ph+ALL with resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec®)

Sunitinib malate (Sutent®) is denied when **all** of the following exclusion criteria are present:

- No documentation of a diagnosis of gastrointestinal stromal tumors (GIST) after disease progression on imatinib mesylate (Gleevec®) or documented intolerance to imatinib mesylate (Gleevec®)
- No documentation of a diagnosis of advanced renal cell carcinoma (RCC)

Thalidomide (Thalomid®) is denied when **all** of the following exclusion criteria are present:

- No documentation of acute treatment of cutaneous manifestations of moderate-to-severe erythema nodosum leprosum (ENL)
- No documentation of maintenance therapy for prevention and suppression of erythema nodosum leprosum (ENL) occurrence
- No documentation of first-line therapy for multiple myeloma
- No documentation of a diagnosis of neoplastic disease with documented failure of conventional therapy

Erlotinib (Tarceva®) is denied when **all** of the following exclusion criteria are present:

- No documentation of a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and documentation of at least one prior chemotherapy regimen that failed or is contraindicated
- No documentation of a diagnosis pancreatic cancer in combination with gemcitabine (Gemzar®) as a first-line therapy

Vorinostat (Zolinza®) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of cutaneous T-cell lymphoma (CTCL)
- No documentation of the trial and failure of, or contraindication to, at least two systemic therapies

Lapatinib (Tykerb®) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of advanced or metastatic breast cancer
- No documentation of a tumor with overexpression of HER2
- No documentation of concurrent treatment with capecitabine
- No documentation of prior therapy with all of the following:
    - An anthracycline
    - A taxane
    - Trastuzumab (Herceptin®)

Nilotinib (Tasigna®) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of chronic-phase or accelerated-phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML)
- No documentation of resistance to or intolerance to imatinib mesylate (Gleevec®)

Topotecan capsule (Hycamtin®) is denied when **any** of the following exclusion criteria is found:

- No documentation of diagnosis of small cell lung cancer
- No documentation of complete or partial response to one of the following first-line chemotherapy agents:
  - Cisplatin
  - Carboplatin
  - Etoposide
  - Irinotecan
  - Cyclophosphamide
  - Doxorubicin
  - Vincristine
  - Intravenous Topotecan
  - Ifosfamide
  - Paclitaxel
  - Docetaxel
  - Gemcitabine

Policy List of Applicable Drugs

Brand Name	Generic Name
Gleevec	imatinib mesylate
Hycamtin	topotecan
Iressa	gefitinib
Nexavar	sorafenib
Revlimid	lenalidomide
Sprycel	dasatinib
Sutent	sunitinib malate
Tarceva	erlotinib
Thalomid	thalidomide
Zolinza	vorinostat
Tykerb	lapatinib
Tasigna	nilotinib

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

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